Deutscher Bundestag **Drucksache 16/7192**
16. Wahlperiode 15. 11. 2007

Beschlussempfehlung und Bericht

des Ausschusses für Gesundheit (14. Ausschuss)

zu der Unterrichtung durch die Bundesregierung
– Drucksache 16/6389 Nr. 1.10 –

Mitteilung der Kommission an das Europäische Parlament und den Rat
Organspende und -transplantation: Maßnahmen auf EU-Ebene
(inkl. 9834/07 ADD 1)
KOM (2007) 275 endg.; Ratsdok. 9834/07

A. Problem

Die Mitteilung der Europäischen Kommission über Organspende und -transplantation greift die Rechtsgrundlage des Artikels 152 Abs. 4 Buchstabe a des EG-Vertrages (EGV) auf, der das Europäische Parlament und den Rat ermächtigt, harmonisierte Maßnahmen auf der Grundlage des Mitentscheidungsverfahrens gemäß Artikel 251 EGV zu treffen, um hohe Qualitäts- und Sicherheitsstandards für Organe und Substanzen menschlichen Ursprungs festzulegen. Die Europäische Kommission hat in der Mitteilung zentrale Handlungsfelder hinsichtlich Organspende und -transplantation auf der Grundlage des im Juni 2006 durchgeführten Konsultationsverfahrens vorgelegt. Mit Blick auf das hohe Sicherheits- und Qualitätsniveau des Transplantationswesens in Deutschland und die zum Teil sehr unterschiedlichen kulturellen, rechtlichen und organisatorischen Gegebenheiten in der Transplantationsmedizin der einzelnen Mitgliedstaaten stellt sich die Frage nach der Angemessenheit vorgeschlagener Maßnahmen sowie nach den möglichen Auswirkungen ihrer Umsetzung auf das Transplantationswesen in Deutschland.

B. Lösung

Kenntnisnahme der Unterrichtung und Annahme eines Entschließungsantrags. Die Bundesregierung wird aufgefordert, im Rahmen des europäischen Diskussionsprozesses dafür Sorge zu tragen, dass nur solche Regelungen getroffen werden, die das hohe Sicherheits- und Qualitätsniveau im Bereich der Organspende und -transplantation in Deutschland nicht beeinträchtigen und die mit dem Subsidiaritätsprinzip nach Artikel 152 Abs. 5 Satz 2 EGV vereinbar sind.

In Kenntnis der Unterrichtung Annahme einer Entschließung mit den Stimmen aller Fraktionen

C. Alternativen

Kenntnisnahme der Vorlage und gegebenenfalls Annahme einer alternativen Entschließung.

D. Kosten

Wurden im Ausschuss nicht erörtert.

Beschlussempfehlung

Der Bundestag wolle beschließen,

in Kenntnis der Unterrichtung auf Drucksache 16/6389 Nr. 1.10 folgende Entschließung anzunehmen:

„I. Der Deutsche Bundestag stellt fest:

Die Europäische Kommission hat am 30. Mai 2007 eine Mitteilung an das Europäische Parlament und den Rat zu Organspende und -transplantationsmaßnahmen auf EU-Ebene vorgelegt. In der Mitteilung stellt die Europäische Kommission Initiativen auf Gemeinschaftsebene vor, um die Probleme in Europa im Zusammenhang mit Transplantationsrisiken, Organmangel und illegalem Organhandel zu bewältigen. Folgende Hauptaktionsschwerpunkte wurden vorgestellt:

– Aktionsplan zur verstärkten Zusammenarbeit zwischen den Mitgliedstaaten im Bereich der Organspende und -transplantation, um gemeinsame Ziele zu ermitteln und zu entwickeln, für die ein gemeinschaftliches Vorgehen erforderlich ist,

– Vorschlag der Europäischen Kommission zu einem EU-Rechtsinstrument über Qualität und Sicherheit von Organspende und -transplantation und

– weiterhin aufmerksame Verfolgung aller Entwicklungen im Bereich des illegalen Organhandels sowohl in der EU als auch weltweit.

Der Deutsche Bundestag nimmt die Mitteilung der Europäischen Kommission an das Europäische Parlament und den Rat Organspende und -transplantationsmaßnahmen auf EU-Ebene zur Kenntnis und teilt die Auffassung der Europäischen Kommission, dass vor allem der Organmangel ein grundlegendes Problem der transplantationsmedizinischen Versorgung in den EU-Mitgliedstaaten ist.

Der Deutsche Bundestag begrüßt die Initiative der Europäischen Kommission, einen Aktionsplan mit Maßnahmen zum Bereich Organspende und -transplantation vorzulegen; dabei sind die Sicherstellung eines hohen Gesundheitsschutzniveaus für alle Patientinnen und Patienten in ganz Europa sowie die Umsetzung von Maßnahmen zur Behebung des Organmangels in Europa von Priorität.

Der Deutsche Bundestag stimmt mit der Europäischen Kommission darin überein, dass innerhalb Europas höchst unterschiedliche kulturelle, rechtliche und organisatorische Gegebenheiten vorliegen und die Realisierung eines hohen Qualitäts- und Sicherheitsniveaus in allen europäischen Mitgliedstaaten bei der Organspende und -transplantation zum Wohle der schwerkranken Patientinnen und Patienten gefördert und weiter vorangetrieben werden muss.

Der Deutsche Bundestag weist darauf hin, dass die Organspende und -transplantation mit komplexen Fragen von ethischer Tragweite verbunden ist und in den Mitgliedstaaten aufgrund der jeweiligen kulturellen, rechtlichen und organisatorischen Gegebenheiten unterschiedlich behandelt wird.

Er begrüßt den Vorschlag eines Aktionsplans zur verstärkten Zusammenarbeit zwischen den Mitgliedstaaten im Bereich der Organspende und -transplantation, um vor allem die Mitgliedstaaten zu unterstützen, die nicht über eine ausreichende transplantationsmedizinische Versorgung verfügen und unterstützt den gegenseitigen Erfahrungsaustausch über Maßnahmen zur Erhöhung der Organspendebereitschaft sowie über die Organisation der Organspende und -transplantation in den jeweiligen Mitgliedstaaten, um die Verfügbarkeit von

Organen und die Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme zu erhöhen und eine gerechte, nur nach medizinischer Indikation erfolgende Organallokation sicherzustellen.

Der Deutsche Bundestag stellt fest, dass das Transplantationswesen in Deutschland, wie in anderen Mitgliedstaaten mit etablierten Transplantationssystemen, auf einem hohen Sicherheits- und Qualitätsniveau ist und verweist auf den Artikel 152 Abs. 5 Satz 2 des EG-Vertrages, wonach die einzelstaatlichen Regelungen über die Spende oder die medizinische Verwendung von Organen unberührt bleiben.

II. Der Deutsche Bundestag bittet die Bundesregierung, den europäischen Diskussionsprozess konstruktiv zu begleiten und darauf hinzuwirken, dass

1. bei den Beratungen über einen europäischen Rechtsrahmen für Qualität und Sicherheit menschlicher Organe auf der Grundlage von Artikel 152 Abs. 4 Buchstabe a EGV keine europäischen Regelungen getroffen werden, die letztlich die notwendige Versorgung der auf eine Organtransplantation angewiesenen Patienten beeinträchtigen können oder die mit dem Subsidiaritätsprinzip in Artikel 152 Abs. 5 Satz 2 EGV nicht vereinbar sind,

2. die deutschen Erfahrungen bei den Beratungen über die Qualität und Sicherheit im Bereich der Organspende und -transplantation eingebracht werden mit dem Ziel, europaweit ein hohes Sicherheits- und Qualitätsniveau zu erreichen,

3. die einzelstaatlichen gesetzlich-ethischen Regelungen über die Spende von Organen unberührt bleiben.“

Berlin, den 14. November 2007

Der Ausschuss für Gesundheit

Dr. Martina Bunge	**Dr. Konrad Schily**
Vorsitzende	Berichterstatter

Bericht des Abgeordneten Dr. Konrad Schily

I. Überweisung

Die Mitteilung der Kommission zu Organspende und -transplantation – KOM (2007) 275 endg.; Ratsdok. 9834/07 – wurde mit **Drucksache 16/6389 Nr. 1.10** vom 19. September 2007 gemäß § 93 Abs. 1 GO-BT dem Ausschuss für Gesundheit zur Beratung überwiesen.

II. Wesentlicher Inhalt der Vorlage

Die Mitteilung der Kommission über Organspende und -transplantation greift die Rechtsgrundlage des Artikels 152 Abs. 4 Buchstabe a EGV auf, der das Europäische Parlament und den Rat ermächtigt, harmonisierte Maßnahmen auf der Grundlage des Mitentscheidungsverfahrens gemäß Artikel 251 EGV zu treffen, um hohe Qualitäts- und Sicherheitsstandards für Organe und Substanzen menschlichen Ursprungs festzulegen. In der Mitteilung werden die Initiativen auf Gemeinschaftsebene vorgestellt, die die Europäische Kommission in Bezug auf die Organspende und -transplantation in Europa zu ergreifen beabsichtigt: Festlegung eines Qualitäts- und Sicherheitsrahmens für Organspende und -transplantation, Förderung der Zusammenarbeit zwischen den Mitgliedstaaten, um die Verfügbarkeit von Organen und die Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme zu erhöhen, sowie Bekämpfung des illegalen Organhandels.

III. Beratungsverlauf und Beratungsergebnis

Der **Ausschuss für Gesundheit** hat die Vorlage in seiner 63. Sitzung am 10. Oktober 2007 und in seiner 67. Sitzung am 14. November 2007 beraten. Die Fraktionen der CDU/CSU und SPD brachten in der abschließenden Beratung auf Ausschussdrucksache 16(14)0312 den in der Beschlussempfehlung wiedergegebenen Entschließungsantrag ein, dem die Fraktionen FDP, DIE LINKE. und BÜNDNIS 90/DIE GRÜNEN beigetreten sind. Im Ergebnis der Beratungen empfiehlt der Ausschuss in Kenntnis der Unterrichtung durch die Bundesregierung mit den Stimmen aller Fraktionen, die in der Beschlussempfehlung wiedergegebene Entschließung anzunehmen.

Alle Fraktionen äußerten übereinstimmend die Auffassung, dass mit Blick auf die Bundesrepublik Deutschland eine EU-Richtlinie ebenso wie eine gesetzliche Regelung auf europäischer Ebene zum Thema Organtransplantation nicht erforderlich sei. Man sei in erster Linie daran interessiert, die Qualitäts- und Sicherheitsstandards, die in Deutschland bereits erreicht worden seien, zu erhalten. Es gehe darum, dem Subsidiaritätsprinzip in dieser Frage Geltung zu verschaffen und dafür zu sorgen, dass die einzelstaatlichen gesetzlich-ethischen Regelungen über die Organspende durch etwaige neue Regelungen auf EU-Ebene unberührt blieben. Die Fraktion der FDP wies ergänzend darauf hin, dass sie das Anliegen der Euroäischen Kommission teile, die Möglichkeit der Lebendspende zu erweitern, dies aber im nationalen Rahmen zu regeln sei.

Berlin, den 14. November 2007

Dr. Konrad Schily
Berichterstatter

Anlage

RAT DER EUROPÄISCHEN UNION

Brüssel, den 4. Juni 2007 (13.06) (OR. fr)

9834/07

SAN 108

ÜBERMITTLUNGSVERMERK

Absender:	Herr Jordi AYET PUIGARNAU, Direktor, im Auftrag des Generalsekretärs der Europäischen Kommission
Eingangsdatum:	31. Mai 2007
Empfänger:	der Generalsekretär/Hohe Vertreter, Herr Javier SOLANA
Betr.:	Mitteilung der Kommission an das Europäische Parlament und den Rat Organspende und -transplantation: Massnahmen auf Eu-Ebene

Die Delegationen erhalten in der Anlage das Kommissionsdokument - KOM(2007) 275 endgültig

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Anl.: KOM(2007) 275 endgültig

KOMMISSION DER EUROPÄISCHEN GEMEINSCHAFTEN

Brüssel, den 30.5.2007
KOM(2007) 275 endgültig

MITTEILUNG DER KOMMISSION
AN DAS EUROPÄISCHE PARLAMENT UND DEN RAT

ORGANSPENDE UND -TRANSPLANTATION: MASSNAHMEN AUF EU-EBENE

{SEK(2007) 704}
{SEK(2007) 705}

1. EINLEITUNG

In den letzten 50 Jahren hat sich die Organtransplantation weltweit etabliert und Hunderttausenden von Patienten ungeheuren Nutzen gebracht.

Organspende und –transplantation sind heikle und komplexe Fragen von ethischer Tragweite, deren Ausbau der umfassenden gesellschaftlichen Mitwirkung bedarf. In verschiedenen Aspekten werden diverse Aspekte je nach kulturellen, rechtlichen, administrativen und organisatorischen Gegebenheiten unterschiedlich behandelt.

Die Zahl der Transplantationen menschlicher Organe ist in den letzten Jahrzehnten ständig angestiegen. Mittlerweile stellt die Organtransplantation die kostengünstigste Behandlung bei Nierenversagen im Endstadium dar; bei Leber-, Lungen- und Herzversagen ist sie zurzeit die einzige Behandlungsmöglichkeit.

Durch die hervorragenden Ergebnisse, die mit Transplantationen in Bezug auf gewonnene Lebensjahre und Verbesserung der Lebensqualität erzielt wurden, haben sich die Indikationen dieser Therapien vervielfacht. Transplantationsverfahren werden immer noch weiter entwickelt und können in Zukunft praktische Therapiemöglichkeiten für weitere bisher unbehandelbare Erkrankungen bieten.

Der therapeutische Einsatz von Organen bringt jedoch auch ein Risiko der Krankheitsübertragung mit sich. Jedes Jahr wird eine Reihe von Organen unter den EU-Mitgliedstaaten ausgetauscht. Grenzübergreifender Austausch bedeutet, dass die Transplantationsverfahren von Krankenhäusern oder Ärzten durchgeführt werden, für die unterschiedliche Rechtsordnungen gelten.

Andererseits beeinträchtigt der Organmangel die Transplantationsprogramme in hohem Maße. Beinahe 40 000 Patienten stehen zurzeit in Europa auf den Wartelisten. Die Sterblichkeitsraten während der Wartezeit für eine Herz-, Leber- oder Lungentransplantation betragen in der Regel zwischen 15 und 30 %. Innerhalb der EU ist die Rate der verstorbenen und lebenden Spender höchst unterschiedlich. Diese Unterschiede sind nicht leicht zu erklären. Selbst in EU-Mitgliedstaaten, die über hoch entwickelte Gesundheitsdienste verfügen, gibt es beträchtliche Unterschiede bei der Organspende und –transplantation, und einige Organisationsmodelle scheinen leistungsfähiger zu sein als andere.

Eine der möglichen Folgen der Organknappheit besteht im illegalen Handel mit menschlichen Organen durch kriminelle Gruppen, die Organe in Entwicklungsländern ausfindig machen und entnehmen, um sie dann an Empfänger in der Europäischen Union zu vermitteln.

Die vorliegende Mitteilung der Kommission über Organspende und -transplantation soll diese Problematik auf der Rechtsgrundlage des Artikels 152 Absatz 4 Buchstabe a EG-Vertrag aufgreifen, dem zufolge das Europäische Parlament und der Rat harmonisierte Gesundheitsschutzmaßnahmen auf der Grundlage des Mitentscheidungsverfahrens gemäß Artikel 251 EG-Vertrag treffen können, um hohe Qualitäts- und Sicherheitsstandards für Organe menschlichen Ursprungs festzulegen. In der Mitteilung werden die Maßnahmen dargestellt, welche die Kommission plant, um auf die hauptsächlichen politischen Herausforderungen in Bezug auf Organspende und -transplantation zu reagieren: Sicherstellung der Qualität und Sicherheit von Organen, Erhöhung der Spendenbereitschaft und Bekämpfung des illegalen Organhandels.

2. ORGANSPENDE UND -TRANSPLANTATION: DIE AKTUELLE PROBLEMATIK

2.1. Transplantationsrisiken

Der therapeutische Einsatz von Organen bringt das Risiko einer Krankheitsübertragung auf den Empfänger mit sich. In der wissenschaftlichen Literatur wurde die Übertragung von HIV, Hepatitis B und C, Bakterien, Pilzen und Parasiten durch die Transplantation beschrieben, ebenso wie die Übertragung verschiedener Krebsarten.

Die Übertragung einer Krankheit durch das Organ eines verstorbenen Spenders kann nicht nur zum Verlust des Transplantats, sondern auch zum Tod des Empfängers führen, dessen Immunreaktion ja unterdrückt wird. Trotz des Mangels an Organen verstorbener Spender muss jedes Organ gründlich geprüft werden.

Jedes Jahr wird eine Reihe von Organen zwischen den EU-Mitgliedstaaten ausgetauscht. Die Zahl der ausgetauschten Organe macht nur einen kleinen Anteil der gesamten in der EU transplantierten Organe aus, mit Ausnahme der unter internationale Vereinbarungen (Eurotransplant) fallenden Bereiche, in denen der Organaustausch bis zu 20 % der gesamten Organtransplantationen ausmacht. Darüber hinaus lassen sich jedes Jahr eine Reihe von EU-Bürgern in einem anderen Mitgliedstaat als ihrem Heimatland ein Organ transplantieren. Die Zahl der Patienten, die versuchen, in einem anderen Land mit größerer Spendenbereitschaft eine Organspende zu erhalten, ist offenbar im Steigen begriffen. Allerdings gelten in den einzelnen Mitgliedstaaten unterschiedliche Qualitäts- und Sicherheitsanforderungen[1]. Die Sicherstellung eines hohen Gesundheitsschutzniveaus für alle Patienten in ganz Europa stellt daher eine Priorität dar.

2.2. Organmangel

Der gravierende Mangel an Organspendern ist auch weiterhin das Hauptproblem, vor dem die EU-Mitgliedstaaten bei der Organtransplantation stehen.

In Europa sterben täglich beinahe zehn Patienten, die auf ein Organ warten. In allen EU-Mitgliedstaaten werden die Wartelisten immer länger. Selbst in Fällen, in denen die Zahl der Spender stetig angestiegen ist, erweist es sich als sehr schwierig, die Zahl der Patienten auf den Wartelisten und die Wartezeiten zu verringern. Die Nachfrage nach Transplantationen steigt schneller als die Spendenbereitschaft. Dennoch wird die steigende Zahl der Spender dazu beitragen, die Kluft zwischen Angebot und Nachfrage zu verringern, auch wenn sich die absoluten Zahlen auf den Wartelisten nicht senken lassen.

Für den Mangel an Spendern gibt es verschiedene Gründe[2]. Auch sind die Mitgliedstaaten bei ihren Bemühungen zur Erhöhung der Spendenbereitschaft unterschiedlich erfolgreich. Die Spenderraten variieren erheblich von einem europäischen Land zum anderen: die Rate der verstorbenen Spender reicht von 0,8 bis 35,1 Spendern je Million Einwohner. Diese Unterschiede sind nicht leicht zu erklären. Sie beruhen wahrscheinlich auf einer komplexen Kombination kultureller, historischer und sozialer Faktoren, zusammen mit Aspekten des Gesundheitswesens und der Organisation des Spendenwesens im jeweiligen Land.

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1 http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf.

2 Nähere Einzelheiten sind der Folgenabschätzung im Anhang zu dieser Mitteilung zu entnehmen.

2.3. Illegaler Organhandel

Wie bereits erwähnt, ist das Angebot an Organen sehr begrenzt.

Zwar hat die strafrechtliche Verfolgung bisher keine Nachweise erbracht, doch es ist möglich, dass international agierende kriminelle Organisationen die lukrativen Möglichkeiten erkannt haben, die sich aus der Lücke zwischen Angebot und Nachfrage ergeben, und mehr Druck auf Menschen ausüben, die in extremer Armut leben, damit diese ihre Organe verkaufen.

Das Problem des Organhandels ist nicht neu auf der Welt. In den 80er Jahren wurden Fachleute auf ein Phänomen aufmerksam, das als „Transplantationstourismus“ bekannt wurde. Dabei reisten wohlhabende Asiaten nach Indien und in andere Teile Südostasiens, um Organe von in Armut lebenden Spendern zu erhalten. Seither haben sich andere Möglichkeiten eröffnet.

Zwar bewegt sich der Organhandel in Europa nach aktuellen Schätzungen auf relativ bescheidenem Niveau, dennoch gibt die Problematik Anlass zu ernster politischer und ethischer Besorgnis.

3. Der Mehrwert der EU-Massnahmen

In den letzten Jahren hat die Kommission erhebliche Anstrengungen unternommen, um die Organtransplantation im Rahmen verschiedener Gemeinschaftsprogramme zu unterstützen. Es wurde eine große Zahl von Projekten gefördert[3], deren Ergebnisse beträchtliche Mengen an Informationen und Erkenntnissen geliefert haben, welche für die Durchführung von EU-Maßnahmen in diesem Bereich von Nutzen sein können. Es wird nun Zeit, diese Erkenntnisse umzusetzen.

Im Juni 2006 leitete die Kommission eine öffentliche Anhörung zum Thema Organspende und -transplantation ein. Anhand der Ergebnisse dieser Anhörung schlägt die Kommission nun vor, weitere Initiativen auf Gemeinschaftsebene zu treffen, die zur Bewältigung der vor uns liegenden Herausforderungen einen Mehrwert erbringen.

Im Mittelpunkt der Gemeinschaftsmaßnahmen in diesem Bereich steht die Gewährleistung von Qualität und Sicherheit menschlicher Organe, da dieser Aspekt im Vertrag zur Gründung der Europäischen Gemeinschaft Vorrang erhalten hat[4]. Eine von der italienischen Regierung während ihres EU-Ratsvorsitzes 2003 veranstaltete Expertenkonferenz nannte den Organmangel und den Organhandel als Hauptprioritäten in diesem Bereich und unterstrich, dass Qualitäts- und Sicherheitsaspekte im Rahmen von Organangebot und -nachfrage umfassend zu berücksichtigen sind. Um die genannten Herausforderungen angemessen bewältigen zu können, bedarf es eines integrierten Vorgehens mit drei Aktionen.

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3 Eine Beschreibung der Projekte ist der Folgenabschätzung im Anhang zu dieser Mitteilung zu entnehmen.

4 Seit 1999 ermöglicht Artikel 152 EGV es dem Europäischen Parlament und dem Rat, Gesundheitsschutzmaßnahmen anzunehmen, die hohe Qualitäts- und Sicherheitsstandards für Organe und Substanzen menschlichen Ursprungs, Blut und Blutderivate festlegen. Die Gemeinschaft hat bereits Richtlinien des Parlaments und des Rates für Blut sowie für Gewebe und Zellen festgelegt.

3.1. Qualitäts- und Sicherheitsrahmen für Organspende und -transplantation

In jeder Phase des Transplantationsverfahrens lässt sich eine Reihe von Maßnahmen durchführen, um die Qualität und die Sicherheit der Organe zu verbessern.

Ein wesentlicher Bestandteil einer soliden Organtransplantation besteht darin, die potenziellen Spender vor der Transplantation zu untersuchen. Diese Untersuchung muss genügend Informationen liefern, damit das Transplantationsteam eine angemessene Nutzen-Risiko-Analyse erstellen kann. Die Risiken und Merkmale des Organs sind zu ermitteln und zu dokumentieren, damit das Organ einem geeigneten Empfänger zugeteilt werden kann.

Als wesentliche Schritte in Richtung auf Qualität und Sicherheit haben sich Aufzeichnungen über Spender und Qualitätssysteme erwiesen. Es müssen Standardverfahren für die Entnahme und Vorschriften für die Aufbewahrung und den Transport von Organen vorhanden sein.

Sicherzustellen ist ein geeigneter Transport der Organe, der Zeiten ohne Blutversorgung minimiert und Organschädigungen vermeidet. Bei gleichzeitiger Wahrung der medizinischen Vertraulichkeit muss der Organbehälter klar beschriftet werden und die erforderliche Dokumentation enthalten.

Das Transplantationssystem muss sicherstellen, dass die Spur vom Spender zum Empfänger verfolgt werden kann. Das System muss im Falle einer unvorhergesehenen Komplikation warnen können. Zudem muss ein System vorhanden sein, mit dem sich ernste oder unvorhersehbare unerwünschte Zwischenfälle erkennen und untersuchen lassen.

Ein Organspender ist oft auch ein Gewebespender. Die Qualitäts- und Sicherheitsanforderungen für Organe sollten mit dem bestehenden Gemeinschaftssystem für Gewebe und Zellen[5] verbunden werden und dieses ergänzen. Eine unerwünschte Reaktion beim Empfänger einer Organspende sollte zurückverfolgt und bei Bedarf über das Gewebevigilanzsystem gemeldet werden.

Es wurde bereits betont, welche Schlüsselrolle die einzelstaatlichen zuständigen Behörden bei der Gewährleistung von Qualität und Sicherheit dieses Verfahrens spielen, und ebenso, wie wichtig es ist, Systeme für die Zulassung von Einrichtungen sowie Programme für Organspende und -entnahme auf der Grundlage gemeinsamer Qualitäts- und Sicherheitskriterien zu schaffen. Dieses System sollte eine vollständige Liste aller zugelassenen Zentren in ganz Europa liefern, auf die sowohl die Öffentlichkeit als auch Angehörige der Gesundheitsberufe Zugriff haben.

Verbindliche Sicherheits- und Qualitätskriterien sollten nicht zur Senkung der Zahl der Spender führen. Es ist wichtig, über das Krankheitsübertragungsrisiko, das mit jedem Fall einhergeht, Klarheit zu gewinnen. Zwar ist eine Risikodefinition anhand des Spenderprofils für eine rationale Entscheidungsfindung entscheidend, doch jede Entscheidung hängt auch von den Merkmalen des Empfängers ab. In jedem Einzelfall sind Nutzen und Risiken gegeneinander abzuwägen: das mit dem Organ verbundene Risiko gegen die Folgen, wenn keine Transplantation erfolgt.

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5 Richtlinie 2004/23/EG des Europäischen Parlaments und des Rates vom 31. März 2004 zur Festlegung von Qualitäts- und Sicherheitsstandards für die Spende, Beschaffung, Testung, Verarbeitung, Konservierung, Lagerung und Verteilung von menschlichen Geweben und Zellen (ABl. L 102 vom 7.4.2004, S. 48).

3.2. Zusammenarbeit zwischen den Mitgliedstaaten

Organmangel ist ein gemeinsames Problem aller Länder Europas, und der Knowhow-Transfer innerhalb der EU hat sich in einigen Ländern zur Erhöhung der Spenderraten bereits als sinnvoll erwiesen.

3.2.1. Organangebot

Einige Mitgliedstaaten haben verschiedene Initiativen eingeführt, in deren Mittelpunkt Organisation und Praxis von Spendesystemen stehen, mit denen nachweislich das Organangebot erhöht werden konnte.

Ein wichtiger Faktor zur Ermittlung von Personen, die zur Spende nach ihrem Tode bereit sind, sobald alle obligatorischen Zustimmungsanforderungen der jeweiligen Mitgliedstaaten erfüllt sind, besteht offenbar darin, ein leistungsfähiges System einzurichten, das verstorbene potenzielle Spender ermittelt und zu tatsächlichen Spendern macht. Es hat sich gezeigt, dass viele Spender verloren gehen, weil keine Überprüfung oder keine Meldung stattfindet oder weil es versäumt wird, den Angehörigen eine Organspende nahezulegen.

In manchen Mitgliedstaaten hat die Fortbildung und Beschäftigung von für die Ermittlung potenzieller verstorbener Organspender und die Organisation des Organspendeverfahrens zuständigen Beschäftigten des Gesundheitswesens die Leistungsfähigkeit der Organbeschaffung erhöht und dazu geführt, dass die Transplantationssysteme besser funktionieren.

Um den Spenderkreis zu erweitern, wäre es wichtig, die Förderung der altruistischen Lebendspende zu erwägen, und zwar auf der Grundlage angemessener Sicherheitsvorkehrungen zum Schutz der lebenden Spender und zur Verhinderung illegalen Organhandels. Lebendspenden liegen in Europa bei 17 % der Nierentransplantationen und bei 5 % der Lebertransplantationen vor. Obgleich lebende Spender immer schon von entscheidender Bedeutung für die Transplantation waren, ist der Einsatz von Lebendspendern in den letzten Jahren drastisch gestiegen. Der Anstieg der Lebendspenden ist auf mehrere Faktoren zurückzuführen, unter anderem auf den Druck durch den Mangel an Spenderorganen von Verstorbenen, auf Fortschritte in der Chirurgie und überzeugende Nachweise günstiger Transplantationsergebnisse und geringer Spenderrisiken. Die Zahl der freiwilligen Lebendspendern ist innerhalb Europas ebenfalls höchst unterschiedlich.

Unter bestimmten Umständen wäre es auch möglich, andere potenzielle Spender (einen „erweiterten Spenderkreis“) in Erwägung zu ziehen, die aufgrund einer positiven Serologie, angeborener oder erblicher Gesundheitsstörungen, familiärer Belastung oder anderer Merkmale wie Spenderalter, Bluthochdruck oder Diabetes keine idealen Spender wären.

3.2.2. Das Bewusstsein der Öffentlichkeit

Das Bewusstsein der Öffentlichkeit und die öffentliche Meinung spielen ebenfalls eine wichtige Rolle bei der Verstärkung der Spendenbereitschaft.

Organspende und -transplantation sind therapeutische Maßnahmen, an deren Entwicklung die gesamte Gesellschaft mitwirken muss. In diesem Bereich gibt es viele komplexe und heikle Fragen der Ethik, und es ist deutlich geworden, dass mehrere dieser Aspekte in den

verschiedenen Ländern je nach den kulturellen Wertvorstellungen unterschiedlich behandelt werden.

Im Jahre 2006 erklärten sich 56 % der Europäer bereit[6], ihre Organe nach dem Tode einem Organspendedienst zur Verfügung zu stellen. Die Antworten auf die Befragung waren je nach Land höchst unterschiedlich.

Die Quoten der Ablehnungen einer Organspende Verstorbener durch die Angehörigen betragen in Europa zwischen 6 % und 42 %. Auch diese Unterschiede sind nicht leicht zu verstehen. Sie ließen sich erklären durch die große Vielfalt der Verfahren zur Einholung der Zustimmung des Spenders – bei lebenden und verstorbenen Spendern – unterschiedliche organisatorische Praxis sowie andere wichtige kulturelle, wirtschaftliche oder soziale Faktoren, die einen Einfluss darauf haben, wie die Gesellschaft den Nutzen der Organspende wahrnimmt.

Die kostengünstigste Möglichkeit, die Spendenbereitschaft der Öffentlichkeit zu erhöhen, scheint darin zu bestehen, die Beschäftigten im Gesundheitswesen und die Medien besser über Transplantationsfragen zu informieren. Da sowohl positive als auch negative Botschaften die Spendenbereitschaft beeinflussen können, bedarf es einer professionellen Einstellung gegenüber der Spende und der Unterstützung durch Kommunikationsexperten.

Fortgesetzte Aufklärung sollte ein wesentliches Element jeder Kommunikationsstrategie sein. Die Menschen sollten dazu ermutigt werden, über die Organspende zu sprechen und ihren Angehörigen ihre Wünsche mitzuteilen. Nur 41 % der europäischen Bürger haben mit ihren Angehörigen über eine mögliche Organspende gesprochen[6]. Es besteht ein wichtiger Zusammenhang zwischen der Spendenbereitschaft und der Tatsache, darüber mit seinen Familienangehörigen gesprochen zu haben.

Die Schaffung eines europäischen Spenderausweises, dem zu entnehmen ist, ob der Inhaber zur Organspende bereit ist oder nicht, wird dazu beitragen, die Öffentlichkeit für die Problematik zu sensibilisieren. 81 % der europäischen Bürger sprechen sich für die Verwendung eines Spenderausweises aus, damit leichter ermittelt werden kann, wer bereit ist, nach dem Tode Organe zu spenden. Dennoch haben bisher lediglich 12 % der Europäer einen Spenderausweis.

3.2.3. Organisatorische Aspekte

Ein Vergleich der einzelnen Länder zeigt, dass die Spenderraten nicht immer mit den Prozentsätzen derjenigen übereinstimmen, die zuvor in diesen Ländern ihre Spendenbereitschaft erklärt haben. Dies zeigt deutlich, wie wichtig ein leistungsfähiges Transplantationssystem ist, um sicherzustellen, dass die Organe der spendenbereiten Personen auch zur Verfügung gestellt werden.

Voraussetzung für jegliche Maßnahme in diesem Bereich ist die Schaffung geeigneter Transplantationssysteme auf einzelstaatlicher Ebene. Ein solches System braucht einen angemessenen Rechtsrahmen, einen guten fachlichen Ansatz und organisatorische Unterstützung. Die Rolle der zuständigen Behörden ist entscheidend bei der Organisation. Die

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6 Eurobarometer-Umfrage 2006.

Behörden müssen dafür sorgen, dass die grundlegenden Standards eingehalten werden, und sie müssen die Spende- und Transplantationsaktivitäten organisieren.

Die verschiedenen Organisationssysteme in Europa sind das Ergebnis ihrer Ursprünge und ihrer Geschichte. Selbst in den EU-Ländern, die über hoch entwickelte Gesundheitsdienste verfügen, gibt es beträchtliche Unterschiede bei der Organspende und –transplantation, und einige Organisationsmodelle scheinen leistungsfähiger zu sein als andere.

Organtransplantationen unterliegen starkem Zeitdruck. Das Verfahren von der Beschaffung bis zur Transplantation sollte in einigen wenigen Stunden abgeschlossen sein (um das Organ lebensfähig zu erhalten). Zudem muss der Spender zum Empfänger passen, damit ein Organ transplantiert werden kann. Deshalb ist die Organisationsstruktur ein Schlüsselelement der Organspende-/Organtransplantationssysteme.

Als Teil dieser Organisation ist ein wirksames Zuteilungssystem von wesentlicher Bedeutung. Dieses System muss die kurze Zeit berücksichtigen, in der die Organe lebensfähig erhalten werden können, und die Notwendigkeit, sicherzustellen, dass das Organ nach vorher definierten Kriterien dem geeignetsten Empfänger zugeteilt wird.

Die neuen Mitgliedstaaten stehen vor größeren gesundheitlichen Problemen als die übrige Union, haben jedoch weniger wirtschaftliche Ressourcen zu deren Bewältigung. Ihre Gesundheitssysteme stehen deshalb unter besonderem Druck, insbesondere, was das Verfahren von der Organspende bis zur Transplantation angeht, dessen Komplexität besondere Schwierigkeiten verursachen kann. Dies führt zu enormen Unterschieden zwischen den einzelnen Mitgliedstaaten, was den Zugang zu Transplantationen und die Länge der Wartelisten betrifft. Diese Systeme können besonders von einer Zusammenarbeit auf EU-Ebene profitieren.

Es ist allgemein anerkannt, dass sich Spender und Empfänger umso besser aufeinander abstimmen lassen, je größer der Spenderkreis ist. Dringlichkeitspatienten und Problemempfänger (Kinder, hoch sensible Patienten usw.) können innerhalb einer kleinen Organisation nicht wirksam behandelt werden; dies ist besonders in kleinen Mitgliedstaaten problematisch. Gleichzeitig hat auf der Spenderseite die Beteiligung lokaler Akteure (Krankenhaustransplantationsteams und Transplantationskoordinatoren) am Entscheidungsprozess dazu beigetragen, die betreffenden Berufsgruppen zu motivieren, und bessere Ergebnisse hervorgebracht.

Ein flexibles System, das ein dezentralisiertes Netz aus lokalen Organisationen, die sich hauptsächlich auf die Organbeschaffung und die Förderung der Organspende konzentrieren, mit großen Organisationen verbindet, die sich auf die Förderung des Organaustauschs und der Zusammenarbeit konzentrieren, scheint organisatorisch am effektivsten zu sein.

Das Übereinkommen Nr. 26 des Europarats über den Austausch therapeutischer Substanzen menschlichen Ursprungs von 1958 war der Ausgangspunkt für grenzübergreifende Tätigkeiten in diesem Bereich. Die Arbeit des Europarats, von Eurotransplant, Scandiatransplant, des Europäischen Transplantationsnetzes oder die regelmäßigen Sitzungen der Europäischen Organisationen für Organaustausch sind gute Beispiele für die notwendige europäische Zusammenarbeit[7].

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[7] Nähere Einzelheiten sind der Folgenabschätzung im Anhang zu dieser Mitteilung zu entnehmen.

3.3. Bekämpfung des Organhandels

Gemäß Artikel 3 der EU-Charta der Grundrechte hat jeder das Recht auf körperliche Unversehrtheit. Außerdem verbietet die Charta es, den menschlichen Körper und Teile davon zur Erzielung von Gewinnen zu nutzen. Ferner enthält sie das Verbot des Menschenhandels. Als Teil des allgemeinen Phänomens des Menschenhandels stellt der Handel zum Zwecke der Organentnahme einen gravierenden Verstoß gegen die Freiheit und die körperliche Unversehrtheit seiner Opfer dar.

Der Europarat[8] und die Weltgesundheitsorganisation[9] haben bereits mehrfach zu Maßnahmen aufgerufen, um den Organhandel zu bekämpfen. Das Verbot des Handels mit menschlichen Organen und Geweben ist bereits durch internationale Rechtsinstrumente in Kraft gesetzt worden, wie das Übereinkommen von Oviedo über die Menschenrechte und Biomedizin sowie sein Zusatzprotokoll über die Transplantation von Organen und Geweben menschlichen Ursprungs. Außerdem verpflichtet das Protokoll über die Verhütung, Bekämpfung und Bestrafung des Menschenhandels, welches das UN-Übereinkommen zur Bekämpfung des internationalen organisierten Verbrechens ergänzt, die Unterzeichnerstaaten, diese Form des Menschenhandels als Verbrechen zu behandeln und verhältnismäßige und abschreckende Strafen zu erlassen.

Die Kommission bezieht sich ständig auf diese wichtigen internationalen Instrumente und wird alle Entwicklungen im Bereich des illegalen Organhandels sowohl in der EU als auch weltweit aufmerksam verfolgen

4. SCHLUSSFOLGERUNGEN UND FOLGEMASSNAHMEN

Die Arbeit im Rahmen der verschiedenen Gemeinschaftsprogramme wird in den kommenden Jahren fortgesetzt. Wichtig ist, dass die Ergebnisse dieser Projekte auf politischer Ebene weiterverfolgt und gutgeheißen werden; die Ergebnisse müssen allen Beteiligten zur Verfügung gestellt werden.

Die Hauptaktionsschwerpunkte hinsichtlich Organspende und –transplantation sind folgende:

- **Verbesserung von Qualität und Sicherheit**

Die Kommission wird unter Berücksichtigung des bisherigen Dialogs mit den Mitgliedstaaten den genauen, ausgewogenen Umfang des Rechtsrahmens für Qualität und Sicherheit menschlicher Organe festlegen. Dieser Rahmen muss durch die Zusammenarbeit der Mitgliedstaaten gestützt werden; dabei sind ausreichende Informationen zusammenzustellen, anhand deren festgelegt werden kann, welche Risiken beim Einsatz erweiterter Spenderkreise und durch die Förderung guter medizinischer Praxis und die Evaluierung der Posttransplantationsergebnisse („Organvigilanz“) vertretbar sind.

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8 Empfehlung Rec (2004) 7 des Ministerkomitees.

9 Entschließung WHA 42.5 zur Verurteilung des Kaufs und Verkaufs von Organen menschlichen Ursprungs.

- **Erhöhung der Organverfügbarkeit**

Die Kommission wird die Zusammenarbeit zwischen den Mitgliedstaaten fördern, um Erfahrungen und vorbildliche Verfahren auszutauschen, damit leistungsfähige Systeme für die Organspenderermittlung eingerichtet werden können.

Ferner bedarf es der Zusammenarbeit, um die Schulung von im Gesundheitswesen Beschäftigten anhand modellhafter Erfahrungen zu fördern, die Förderung von Lebendspenden zu erwägen und den Einsatz eines erweiterten Spenderkreises (der aus medizinischer Sicht nur für bestimmte Empfänger unter bestimmten Umständen in Frage kommt) unter Berücksichtigung von Qualitäts- und Sicherheitsaspekten zu bewerten.

Zudem wird es von Bedeutung sein, gemeinsame Bemühungen zu unternehmen und Erfahrungen auszutauschen, um das Bewusstsein der Öffentlichkeit zu schärfen. In diesem Zusammenhang ist die Schaffung eines europäischen Organspenderausweises oder dessen Einbeziehung in die bestehende Europäische Krankenversicherungskarte zu erwägen.

- **Erhöhung der Leistungsfähigkeit und Zugänglichkeit der Transplantationssysteme**

Wie auch andere Fragen des Zugangs zur gesundheitlichen Versorgung ist diese Frage im Zusammenhang mit anderen einschlägigen Initiativen auf Gemeinschaftsebene zu betrachten.

Die Initiativen werden sich darauf konzentrieren, die leistungsfähigsten Systeme zu ermitteln, Erfahrungen auszutauschen und vorbildliche Verfahren unter Berücksichtigung lokaler Gegebenheiten zu fördern. Diejenigen Mitgliedstaaten, deren Transplantationssysteme noch nicht ausreichend entwickelt sind, können in ihren Bemühungen zur Verbesserung der Patientenversorgung unterstützt und angeleitet werden.

Weitere Aktionen werden sich darauf richten, den Bedarf für den Organaustausch zwischen einzelstaatlichen Behörden auf EU-Ebene zu ermitteln. Leitlinien für Verfahren zum Angebot überzähliger Organe an andere Länder können unter besonderer Berücksichtigung des Organaustauschs für Dringlichkeits- und Problempatienten bewertet werden.

Die zunehmende Mobilität der EU-Bürger erfordert es, die Hauptprobleme bei der Patientenmobilität zu ermitteln. Auch wird es wichtig sein, EU-weite Vereinbarungen über alle Fragen zu treffen, die die Transplantationsmedizin für Nicht-EU-Bürger betreffen.

Die Kommission schlägt folgende Maßnahmen vor:

- **Aktionsplan zur verstärkten Zusammenarbeit zwischen den Mitgliedstaaten**

Bei der Analyse der Organtransplantationslage in der EU wurden große Unterschiede bei der Rate der verstorbenen und lebenden Spender innerhalb der EU und ebenso große Unterschiede in der Transplantationstätigkeit festgestellt. Diese Unterschiede sind nicht leicht zu erklären, und es ist deutlich geworden, dass einige Modelle leistungsfähiger sind als andere. Der Know-how-Transfer unter den EU-Mitgliedstaaten und die Zusammenarbeit zwischen den Ländern sind noch ausbaufähig, um die Zahl der Organspenden zu maximieren und gleichen Zugang für alle zur Transplantation zu schaffen. Die Gemeinschaft wird das beste der besten Modelle ermitteln und unter Berücksichtigung der kulturellen und organisatorischen Vielfalt dessen EU-weite Anwendung fördern.

Schon in der vom Rat der Gesundheitsminister 1991 angenommenen Entschließung[10] über richtungweisende Entscheidungen in der Gesundheitspolitik hat der Rat die Prüfung eines möglichen Beitrags der Gemeinschaft zur Verfügbarkeit von Transplantationsorganen als eines der Themen genannt, das gemeinsamer Erwägung, regelmäßiger gemeinsamer Erörterung und/oder gemeinsamer Anstrengungen bedarf, um die Mitgliedstaaten bei der Gestaltung ihrer Gesundheitspolitik zu unterstützen. Die wichtigsten europäischen Organaustauschorganisationen haben ebenfalls empfohlen, die besten Initiativen zu ermitteln, um den Erfahrungs- und Informationsaustausch zwischen den EU-Mitgliedstaaten zu fördern und organisatorische Aspekte zu verbessern.

Ein Aktionsplan für engere Zusammenarbeit zwischen den Mitgliedstaaten, der speziell auf diesen konkreten Bereich zugeschnitten ist, wird das nötige politische Instrumentarium liefern, damit man sich schrittweise an die Entwicklung einer EU-Politik annähert. Dieser Ansatz sollte auf der Ermittlung und Entwicklung gemeinsamer Ziele, für die anerkanntermaßen ein gemeinschaftliches Vorgehen erforderlich ist, auf vereinbarten quantitativen und qualitativen Indikatoren und Maßstäben, regelmäßiger Berichterstattung sowie der Ermittlung und dem Austausch vorbildlicher Verfahren beruhen.

- **EU-Rechtsinstrument über Qualität und Sicherheit von Organspende und -transplantation**

Die Gemeinschaft hat bereits Richtlinien des Europäischen Parlaments und des Rates über Qualitäts- und Sicherheitsstandards für Blut[11] sowie für Gewebe und Zellen[12] erlassen. Eine mögliche europäische Richtlinie zur Festsetzung von Qualitäts- und Sicherheitsstandards für Organe könnte ähnliche Fragen behandeln; allerdings ist das Nutzen-Risiko-Verhältnis von grundlegender Bedeutung für die Organtransplantation. Wegen des Organmangels und der lebensbedrohlichen Indikationen für Organtransplantationen ist deren Nutzen hoch und es sind mehr Risiken vertretbar als bei den meisten Behandlungen mit Blut, Geweben und Zellen. In diesem Zusammenhang spielt der Arzt eine wichtige Rolle bei der Entscheidung, ob ein Organ zur Transplantation angenommen wird. Der Vorschlag der Kommission wird diesen Besonderheiten der Organspende und –transplantation Rechnung tragen.

Die Folgenabschätzung im Anhang zu dieser Mitteilung kommt zu dem Schluss, dass ein angemessener und flexibler europäischer Rechtsrahmen auf der Grundlage weiterer Zusammenarbeit mit den Mitgliedstaaten die geeignete Reaktion der Gemeinschaft auf das Mandat gemäß Artikel 152 Absatz 4 Buchstabe a EGV darstellt.

Das künftige Rechtsinstrument, das auf einer eigenen Folgenabschätzung beruht, könnte Grundsätze umfassen, die für die Schaffung eines grundlegenden Qualitäts- und Sicherheitsrahmens erforderlich sind. Dazu gehören

- die Errichtung einer oder mehrerer einzelstaatlichen Aufsichtsbehörden zur Umsetzung der Vorschriften der Richtlinie;
- gemeinsame Qualitäts- und Sicherheitsstandards für die Zulassung von Einrichtungen und Programmen für Organspende und -beschaffung sowie für angemessene Konservierung und Beförderung der Organe;

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10 Entschließung des Rates und der Gesundheitsminister (ABl. C 304 vom 23.11.1991, S. 5).
11 ABl. L 33 vom 8.2.2003, S. 30.
12 ABl. L 102 vom 7.4.2004, S. 48.

– die Sicherstellung der Rückverfolgbarkeit und die Meldung etwaiger schwerer unerwünschter Zwischenfälle und Reaktionen;

– die Einrichtung von Inspektionsstrukturen und Kontrollmaßnahmen;

– die Sicherstellung einer vollständigen Merkmalbeschreibung des Organs, damit das Transplantationsteam eine angemessene Risikobewertung vornehmen kann.

COUNCIL OF THE EUROPEAN UNION

Brussels, 4 June 2007

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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	31 May 2007
to:	Mr Javier SOLANA, Secretary-General/High Representative
Subject:	Commission Staff Working Document Accompanying document to the communication from the Commission to the European Parliament and the Council Organ donation and transplantation: Policy Actions at EU Level Impact Assessment

Delegations will find attached Commission document SEC(2007) 704.

Encl.: SEC(2007) 704

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 30.5.2007
SEC(2007) 704

COMMISSION STAFF WORKING DOCUMENT

Accompanying document to the

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

ORGAN DONATION AND TRANSPLANTATION: POLICY ACTIONS AT EU LEVEL

IMPACT ASSESSMENT

{COM(2007) 275 final}
{SEC(2007) 705}

Lead DG: SANCO

Other involved services: DG ENTR, DG RESEARCH, DG INFSO, DG RELEX, DG JLS, LS and SG

Agenda planning or WP reference: CLWP 2007/2005/SANCO/032

TABLE OF CONTENTS

IMPACT ASSESSMENT[1] ON A COMMISSION COMMUNICATION ON ORGAN DONATION AND TRANSPLANTATION

1. EXECUTIVE SUMMARY

Organ transplantation is the therapeutic use of human organs involving the substitution of a non-functional organ for another one coming from a donor. The use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, and for end-stage failure of organs such liver, lung and heart, it is the only available treatment.

The use of organs in therapy poses a risk of transmission of diseases to the recipient. Infectious or cancerous diseases could be transmitted. Every year, a number of organs are exchanged between EU Member States. Cross border exchanges imply that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions.

In 2003, the Commission carried out a survey on legal requirements related to organ transplantation in the EU. The survey showed discrepancies in quality and safety requirements between Member States[2].

On the other hand, the shortage of organs is a major factor affecting transplantation programmes. Nearly 40 000 patients are now on waiting lists in western Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%. One of the potential consequences of the scarcity of organs is the trafficking of human organs carried out by organised criminal groups, tracking down and removing organs in developing countries and handing them on to recipients within the European Union.

This Commission Communication on Organ donation and transplantation intends to respond to the main policy challenges related to the mandate of Article 152.4 a) of the Treaty, which enables the European Parliament and Council to adopt health measures setting high standards of quality and safety of blood, blood components, organs and substances of human origin

The Community has already adopted Directives of the Parliament and the Council on quality and safety standards for blood in 2003 and for Tissues and Cells in 2004. However, it was already recognized during the discussions of the Tissues and cells Directive that organs need a different approach. In this particular area the main priority is to reduce the organ shortage and the quality and safety aspects have to be considered at the same time that the shortage of organs for the patients in need.

Three levels of possible intervention have been considered. Level one "further work under existing Community programmes." would mean continuing the current level of activity. A second level would consist of implementing an active system of coordination between Member States and stakeholders in order to achieve common objectives, and a third level, building on the previous one, that would add EU legal instruments.

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1 On the basis of SEC (2005) 791 of 15 June 2005 (Impact Assessment Guidelines)
2 http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf

As a conclusion the Commission is proposing a combination of actions oriented to respond to the above mentioned problems. Strengthen the cooperation between Member states will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach will be based, in the first stage at least, on the identification and development of common objectives for which it is agreed that a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices. It will be necessary to determine common EU guidelines for national policy, and formulate the objectives for the short, medium and long term, where necessary in combination with national plans monitoring and comparing national systems, based on a determined set of indicators. It will describe the instruments and methods needed.

A legal framework introducing the basic principles and the technical requirements on donation, procurement, testing preservation, transport and distribution, for human organs will complement the approach taken under the strength cooperation method. The future legal instrument should be limited to those minimum requirements needed to establish a basic quality and safety framework.

To measure the possible impacts of the different options the Commission has used several sources.

– Experience with existing EU legislation on blood and human tissues and cells;

– EU survey on organ donation and transplantation

– Eurobarometer survey on organ donation and transplantation

– Consultation with Member States experts

– Extensive consultation with all stakeholders;

– Relevant publications of other international organisation: Council of Europe, WHO

– Published literature on scientific, economic, regulatory and ethical aspects of organ transplantation

– Conclusions/contributions from the projects funded by Community programmes

This document is to be read together with the draft Communication on Organ donation and transplantation

2. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES.

2.1. Organisation and timing

(1) In 2003, the Commission carried out a survey on legal requirements related to organ transplantation in the EU. The survey showed discrepancies in quality and safety requirements within Member States. Results can be found at: http://europa.eu.int/comm/health/ph_threats/human_substance/documents/organ_survey.pdf

(2) The Greek Presidency of the EU presented in February 2003 an initiative (3), with a view to adopting a Council framework decision concerning the prevention and control of trafficking in human organs and tissues, under the legal basis of Articles 29, 31(e), and 34(2)(b) of the EU Treaty (third pillar). The discussions on the initiative were suspended on Coreper on 22 May, pending further detailed information on the situation, especially based in concrete cases. Europol has been asked to issue a report on the situation of Organ trafficking in the EU

(3) The Venice Conference on Safety and Quality in Organ Donation and Transplantation in the European Union was held on 17-18 September 2003. The Conclusions of the expert conference organised by the Italian government during its Presidency of the EU Council, listed the shortage of organs and organ trafficking as the main priorities in this area and underlined that the quality and safety aspects have to be considered fully within the framework of supply and demand for organs.

(4) With the occasion of the adoption of the Tissues and cells Directive on 31 March 2004, the Commission made the following declaration to be entered in the minutes: "The important differences between organ transplantation and the use of other human substances such as blood, tissues and cells mean that a specific approach for organs in order to ensure safety and quality is necessary. Such an approach in the current situation characterised by shortage of organs has to balance two factors: the need for organs' transplantation which is usually a matter of life and death with the need to ensure high standards of quality and safety. The Commission believes that before considering any proposal it is necessary to conduct a thorough scientific evaluation of the situation regarding organ transplantation. The Commission will present a report on the conclusions of the analysis it undertakes as soon as possible."

(5) During March and April 2005, DG SANCO has identified all projects related with organ transplantation. During these two months the relevant DGs were contacted all projects funded with EC money and their respective project officers were identified. Meetings with the different DGs and project officers were held on May, September and October. As a result the Commission (DG INFSO, RTD and SANCO) organised a Workshop in December 2005 on organ transplantation with the objective of promoting EU cooperation on organ donation and transplantation on the basis of the existing projects. Project coordinators, member states experts and transplantation organisations participated. One of the main conclusions of the workshop was the need for these projects to become operational.

(6) On April 2005 the Commission announced the conduction of an evaluation of the situation regarding organ transplantation to the Inter service group on health (ISGH). An ad-hoc working group on organ transplantation was created within the group. The work linked to the present impact assessment report was supported by this Inter-service Steering Group (ISSG) of the European Commission set up in September 2005. The Group was led by the Directorate General for Health and Consumer Protection (DG SANCO). The following DGs were involved in the exercise, DG RTD, DG ENTR, DG INFSO, DG RELEX, DG AIDCO, DG JLS, SJ and Sec-Gen.

(7) A scoping paper was drafted in August 2005 and has been circulated with the draft proposals for consultation during the autumn 2005. On August the scoping paper on organ donation and transplantation was finalised and approved by the Director general, it also incorporated a time table with the following steps.

(8) On 15 November 2005 the Commission hosted a meeting with key experts on organ transplantation. The objective of the meeting was to discuss the future impact assessment of future community initiatives on organ transplantation. Experts from Eurotransplant; Scandiatransplant, CNT, ONT, Agence de la Biomedicine; Hungaro transplant and UK transplant participated.

(9) In order to give stakeholders and Member States an occasion to put forward their positions related to Organ donation and transplantation DG SANCO launched an open consultation in the public health web site from June to September 2006. The draft proposal of the consultation document were sent to relevant DGs in an informal inter-service consultation and presented to the ISGH. A number of replies have been received so far and comments have been taken into account (results of the consultation below).

(10) A preliminary draft of this Impact assessment has been examined by the Impact assessment board, set up in November 2006 by the President of the Commission, with the mandate to examine and advice on the quality of impact assessment (IA) reports. The board has delivered a favourable opinion on 2 March 2007 with three main recommendations. This has led to a number of modifications in the text oriented to clarify the objectives of the policy proposal and the relations between the different objectives. The justification for a EU action has also been strengthened and clarified in the final version following the recommendations of the board. Some modifications in the structrure of the text were introduced to add clarity.

2.2. EC Funded projects

During the past years, the Commission has put considerable effort into supporting organ transplantation. In the area of Information Society, the Commission is supporting the creation of a European registry on organs, cells and tissues through the EUROCET project. This project is a second phase building on the results of a previous project, EURODONOR. A common and agreed nomenclature will make possible to compare the activity of the different systems at EU level.

In the field of research the Commission has also been very actively involved in this area. ALLIANCE-O, an ongoing project, is the first-ever coordination of donation and transplant national or regional research activities across seven different EU countries, which aims to identify the best possible framework for efficient organ donation and transplantation strategies across Europe.

A third important project, DOPKI, has started this year focusing on improving knowledge and developing applicable methodology that could be used to increase the potential of organ donation. In order to achieve such an objective, the project aims to promote cooperation and sharing of information and practices among seven EU countries.

A fourth interesting project, RISET, is based on basic research oriented to reprogram the immune system for the establishment of tolerance to organ transplants. A filth project is BOTIA, aims at improving the safety of blood and organ supply by creating the research infrastructure to monitor emerging pathogens and develop new screen tests through more cost-effective safe and inexpensive procedures.

A sixth project, TRIE, should start before the end of 2006 and is expected to prepare the groundwork for a possible large-scale initiative in transplantation research in the European Union aiming at improving coordination of national research programmes in transplantation. This project will work closely with ALLIANCE-0."

In the area of Justice, Freedom and Security, under the AGIS program, a project is starting that aims to compile national legislations and identify the main problems and potential solutions to ensure the avoidance of organ trafficking. Under the Public Health Program the Commission is finalizing the negotiation phase of a project intended to develop a EU Training Program on Organ Donation.. A new project has been accepted for funding in 2006 aimed to establish a European common standard framework regarding living donation.

The results of all these projects are providing a considerable amount of information useful for active policies in this area.

2.3. Consultation of experts and stakeholders

Member States authorities in the area of organ transplantation were consulted on the draft texts during a meeting organised in December 2005. The initiative was very well received and the feedback was positive. Comments formulated by the various Member States experts during were integrated into the draft texts.

In order to give stakeholders and Member States an occasion to put forward their positions related to Organ donation and transplantation DG SANCO launched an open consultation in the public health web site from June to September 2006. The objectives of the consultation process have been to gather the opinions and views of the stakeholders on issues to be included in the Communication.

The Commission received 73 contributions. Many of them, in particular the ones from regulators, the medical community and the patients or donors associations are the results of wider consultation.

Contributions have been received from 18 Member States (Austria, Belgium, France, UK, Czech Republic, Finland, Sweden, The Netherlands, Denmark, Germany, Ireland, Italy, Spain, Portugal, Latvia, Hungary, Malta, Slovenia and Poland), Norway, Switzerland, Georgia, US and Argentina.

A full listing of all parties providing comments is given at the end of this document. The participants can be divided into 4 categories:

– Patients or donors associations (15 contribution);

– Transplantation professionals / Scientific associations (26 contributions)

– Governmental bodies;, national ministries, national agencies of transplantation; regional representatives, international institutions and Organ exchange organisations (24 contributions);

– Individuals (4 contributions);

– Others (4 contributions).

All contributions received provided valuable information for the Commission's further action in this field. The summary report and the contributions could be found at:

http://ec.europa.eu/health/ph_threats/human_substance/oc_organs/oc_organs_en.htm

3. Problem definition

The use of human organs for transplantation has steadily increased during the past decades. Organ transplantation is now the most cost-effective treatment for end-stage renal failure, and for end-stage failure of organs such liver, lung and heart, it is the only available treatment. Transplant procedures continue to develop and in the future may offer practical treatment for other unmet medical needs such as diabetes mellitus and some forms of malignant and metabolic diseases.

The use of organs in therapy poses a risk of transmission of diseases to the recipient. Infectious or cancerous diseases could be transmitted. Transmission of HIV, Hepatitis B and C, bacteria, fungi and parasites, as well as new emergent diseases, through transplantation have been described in scientific literature.

On the other hand, the shortage of organs is a major factor affecting transplantation programmes. Nearly 40.000 patients are now on waiting lists in Western Europe. Mortality rates while waiting for a heart, liver or lung transplant usually range from 15 to 30%.

An organ transplant is lifesaving and is in most cases the only available treatment. In terms of quality and safety the benefit-to-risk ratio is a fundamental approach for organ transplantation. Due to the organ shortage and the life threatening indications of organ transplants, the benefits of an organ transplantation are high and more risks can be accepted than with blood or most tissues and cells treatments. In this context the clinical doctor has an important role in the decision on the acceptance of organs for transplantation.

Every year, a number of organs are exchanged between EU Member States. Cross border exchanges imply that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. However the number of organs interchanged between Member States constitutes a low percentage of the total organs used for transplantation.

In 2003, the Commission carried out a survey on legal requirements related to organ transplantation in the EU. The survey showed discrepancies in quality and safety requirements within Member States[2].

From 1999 onwards, Article 152 of the Treaty has enabled the European Parliament and Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives. The Community has already adopted Directives of the Parliament and the Council on blood, and on tissues and cells.

It is recognised that organs need a different approach from blood or tissues. An expert conference on organ transplantation, held in Venice on 17-18 September 2003 organised by the Italian government during its Presidency of the EU Council, listed the shortage of organs and organ trafficking as the main priorities in this area and underlined that the quality and safety aspects have to be considered fully within the framework of supply and demand for organs.

One of the potential consequences of the scarcity of organs is the trafficking of human organs carried out by organised criminal groups, tracking down and removing organs in developing countries and handing them on to recipients within the European Union.

3.1. Quality and safety

The use of organs in therapy poses a risk of diseases being transmitted to the recipient. Ensuring the quality and safety of human organs in Europe is at the core of Community activities in this field, as this aspect is prioritized in the Treaty of the European Union.

In this section it is revised the main risks related with organ transplantation and an analysis of every step in the transplant process, how the introduction of measures into every step can improve the quality and safety of organs and a overview of the situation in Member States.

The Risks

3.1.1. Transmission of Communicable diseases.

The use of organs in therapy poses a risk of communicable diseases being transmitted to the recipient. These risks have been described in the scientific literature: Viral, bacterial, and fungal infections have been transmitted via transplantation of organs. Several types of protozoan and worm parasites have also been transferred via organ transplants. Because organs cannot be subjected to sterilization steps, the risk of infectious disease transmission remains and thorough donor screening and testing is especially important.

Although testing covers a broad range of infections, there are some of primary interest; human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV). A complete revision of the main risks is provided in the Annex I.

3.1.2. Transmission of malignant diseases.

Transmission of different types of cancers through organ transplantation has also been described[3.] In the Annex I there is a revision of the findings of the main international registers that could measure the risk of tumour transmission through organ transplants.

Although the risk of tumoral transmission exists, the frequency of donors with tumors and the frequency of transmission are low. Generally, tumors of high degree of malignancy are more often transmitted from donor to recipient. Whereas, the transmission of tumors of low degree of malignancy or localized tumors is much less frequent. For this reason donors diagnosed of low-grade skin tumors with low capacity for metastasis like basocellular carcinoma and donors diagnosed of spinocellular carcinoma without metastasis could be considered for the donation.

On the other hand, not enough evidence exists to set a period of time in which a donor must be free of the neoplastic disease before being accepted as a donor. This depends on the type and features of the tumor, meaning that decisions should be specific to each case.

When considering organ donors who have a history of solid transplantation, the general biologic behaviour of the tumour type, the histology and stage at time of diagnosis, and the length of the disease-free interval should be considered. Additional caution must be exercised

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3 Consensus Document Criteria for Preventing the Transmission of Neoplastic Diseases in Organ Donation. Organizacion Nacional de Transplantes Spain http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

when considering specific tumour types such as melanoma, breast and lung, which are known to have potential for unpredictable behaviour

<u>The different steps of quality and safety in the transplant process</u>

3.1.3. Donor testing

To minimise the risks (described above) to the recipient, it is essential to screen donors and establish the presence or absence of disease transmission risk in their organs. In order to establish the standard level of donor safety, a minimum set of examinations should be performed, but as shown in the "State of the Art" document (Project ALLIANCE-O: deliverable 4.1), there is no consensus to day for all tests. The tests performed in most countries are:

1. blood cell count with differential cell count;

2. antibody to HIV1 and 2;

3. hepatitis B surface antigen;

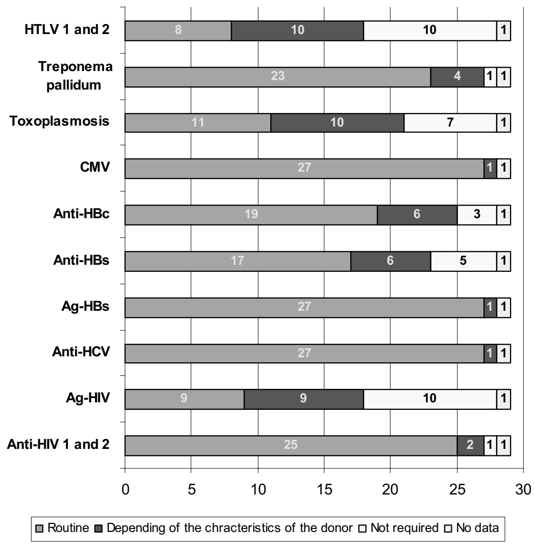
4. antibody to hepatitis C virus;

5. antibody to hepatitis B core antigen;

6. treponemal antigens (VDRL and/or TPHA); a positive result is not a contraindication to organ procurement, but could be a marker of high risk behaviours and than suggests to further investigate for infectious diseases;

7. CMV, EBV and toxoplasmosis are also tested routinely in a majority of countries

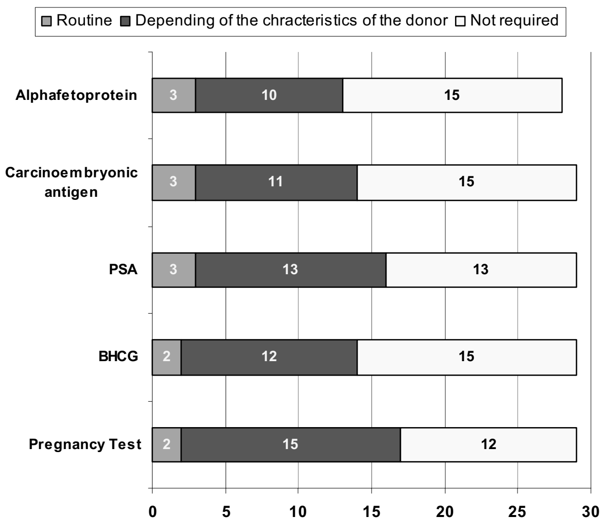
8. The following figure shows the biological tests used in the countries and indicates whether these tests are carried out on a routine basis or depending on donor characteristics2. (Bars indicate the number of countries)



As the previous figure shows, there is consensus in the use of a number of tests (Anti HIV, Anti HCV, Ag-Hbs or Treponema Pallidum), however this does not apply for some other tests (HTLV, Toxoplasmosis or Ag-HIV).

The use of authorised laboratories for carrying out the different tests is a binding requirement in 10 countries[2], although 15 more include this recommendation in technical guidelines. The use of authorised tests for testing the donors is a binding requirement only in seven of the countries surveyed[2]. However, 17 more include this provision in technical guidelines

With respect to tumour markers carried out for donor evaluation, the following figure 14 shows the different practices in the countries surveyed. There is wide heterogeneity, but the results show clearly that few countries carry out these tests on a routine basis[2].



Standard laboratory tests should be conducted on all potential donors with the objective to detect specific malignant diseases that may contraindicate the organ donation. The human chorionic gonadotropin (HCG) beta in the urine should be determined in females in fertile age since this hormone appears augmented in females with choriocarcinoma. Also, it's recommendable, when possible, to do always the determination in a blood sample.

The usefulness of other specific tumoral markers is questionable. With regards to prostate specific antigen (PSA) as screening the adenocarcinoma of the prostate different studies have shown its limited or null usefulness for a premature diagnosis. When selecting donors older than 50 years it was found that only 11 of them (5.9%) had high PSA and only 2 out of those that had high PSA confirmed the presence of adenocarcinoma of the prostate. There is a consensus to advise against indiscriminately carrying PSA and other tumoral markers. For this reason, there isn't any evidence that advices the systematic realization of the PSA for the donor evaluation [4,5,6]

3.1.4. Donor Suitability

Pre-transplant evaluation of potential donors is an essential part of solid organ transplantation. The goals are to identify conditions which disqualify donors; to identify and active infection

4 Frutos MA, Daga D, Ruiz P, Jose Mansilla J, Requena MV. Prostate-specific antigen in the assessment of organ donors. Transplant Proc. 2003 Aug;35(5):1644-6.

5 Ruth Etzioni, David F. Penson, Julie M. Legler, Dante di Tommaso, Rob Boer, Peter H. Gann, and Eric J. Feuer. Overdiagnosis Due to Prostate-Specific Antigen Screening: Lessons From U.S. Prostate Cancer Incidence Trends**.** J Natl Cancer Inst 2002; 94: 981-990

6 Yamey G, Wilkes M. The PSA storm. BMJ 2002; 324: 431.

pre-transplant and to define the level of risk in order to determine strategies for preventing post-transplant effects. The differences on screening between the living donor and the deceased donor are largely based on the different time which this screening takes place. For the living donor it is possible to treat active infection and to defer transplant until such infection resolves. By contract the time frame for deceased donor evaluation is typically hours. Because of the short time frame there is a possibility that certain infections (HIV or HVC) may be presented at an early stage, prior to the development of antibodies. Thus, considerable weight is placed on donor social and medical history in identifying potential risks that might not be reflected in serological testing.

Donor suitability criteria should be established according to accepted medical standards. Donor evaluation normally includes an interview with a family or other relevant source, a detailed review of the medical notes, assessment of the medical and behavioural history, full physical examination, post-mortem examination (autopsy) findings, if performed, and laboratory tests. This information should be obtained by a trained professional.

One of the conclusions of the project O-Alliance (deliverable 4.2?) are common guidelines on suitability of the potential donor: Every donor who will undergo the process of organ removal, must be evaluated by the intensive care operators as well as by local coordinators and clinicians responsible for the transplant of the specific organ jointly to their reference centres according with the procedures presented in the adopted O-Alliance safety guidelines. In addition, a copy of protocol has to be kept and filed at the national reference centres.

The evaluation of the suitability of the donor has to be based on:

– medical history;

– physical examination;

– instrumental as well as laboratory tests; the laboratory tests should be conducted on a sample collected before procedures which required haemodilution;

– histological examination and/or post mortem examination with the aim to clarify those issues emerged during the previous evaluation steps or still to be investigated.

– The gathering of all this information is finalised to the best treatment of the patient.

– In accordance with current knowledge the following conditions, if present, are usually considered as complete exclusion criteria for the donor suitability:

– HIV 1 or 2 seropositivity;

– HbsAg and HDV contemporaneous seropositivity;

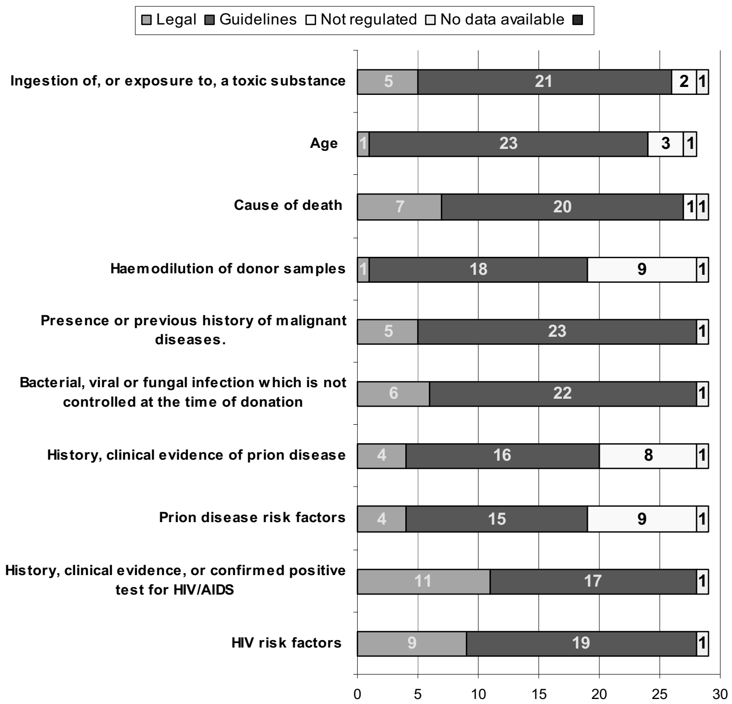
– Current neoplastic conditions (with a number of exceptions);

– Systemic infections caused by agents for which treatments are not feasible;

– Documented prion diseases;

The project concludes that benefit and risk assessment could allow the use of organs at risk for transmissible disease and the final decision of organ suitability should rest with the transplanting team. However, all potential donors should be referred to the donor transplant co-ordinator for assessment. The cause of brain death must always be thoroughly investigated.

In the EU, the criteria for cadaver organ selection are regulated by technical guidelines in most countries2 (23) with only nine having binding selection criteria in place. For the living donor, 13 countries have binding criteria and 15 more have technical guidelines. The next figure shows the different factors included in the risk assessment in the different countries, and how they are regulated (binding requirements, technical guidelines or not regulated).



Most of the risk assessment is governed by technical guidelines. Some of the common accepted criteria such haemodilution of donor samples or risk factors for prion diseases were lacking in a considerable proportion of countries, which do not have any kind of law / guidelines in place.

Evaluation of the different criteria in the risk assessment is covered in technical guidelines in most of the countries surveyed.

There are however some special situations where organ donation could be performed even if the organ does not satisfy all eligibility criteria. These situations occur when the patients condition becomes life threatening and transplantation is the only life-saving treatment possible. Transplantation should be also possible in some specific clinical situations of the recipient, certified by the transplant centre. (O-alliance project delivery 4.2)

3.1.5. Living donors

Living donors of organs will face risks associated both with testing to ascertain their suitability as a donor and the procedure to obtain the organ, tissue or cells. Complications may include medical, surgical, social, financial or psychological problems and, in the worst case

scenario, could seriously incapacitate the donor or even lead to the donor's death. As donors are volunteers and otherwise healthy individuals, all possible measures must be taken to minimise the risks to the donor.

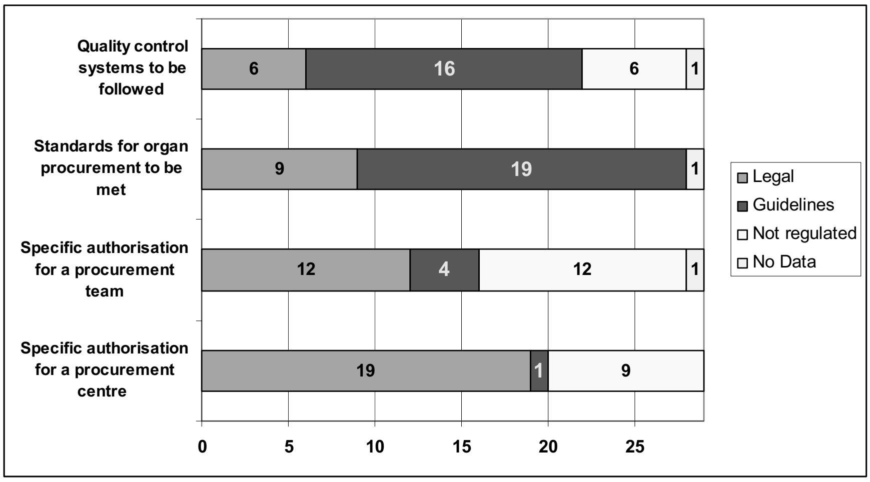
3.1.6. Deceased donor management

The management of the deceased donor during the process is important not only for safety and quality but also for maximising organ procurement. Proper donor management should start as soon as possible after completion of death certification, and while appropriate consent is being obtained to maximise the chance of successful organ recovery the staff involved should have appropriate training and experience. It is recommended that a standardised protocol for donor management be developed in each centre, including monitoring and documentation.

3.1.7. Conditions of procurement

Allograft contamination has been described during procurement, and processing of organs for transplantation. The procurement team has an important role for inspecting the donor in order to complete the donor record. The maintenance of donor records and quality systems has also been identified as key steps towards quality and safety. Standard procedures for procurement and requirements for organ preservation and transport should ensure the best quality and safety.

The following figures show the requirements in the different EU countries in relation with the authorisation of organ procurement, standards for organ procurement and existence of quality systems during the procurement phase.



In order to maximise the benefits and minimise the risks of the transplant procedure, the suitability of an individual donor of organs, tissues or cells should be based upon quality and safety. Organs, tissues and cells should be retrieved and preserved within appropriate time intervals to preserve the necessary biological functions. The time interval should be compatible with the period it takes to perform all the relevant investigations to ensure the quality and safety of the retrieved materials. Therefore, all these activities should be

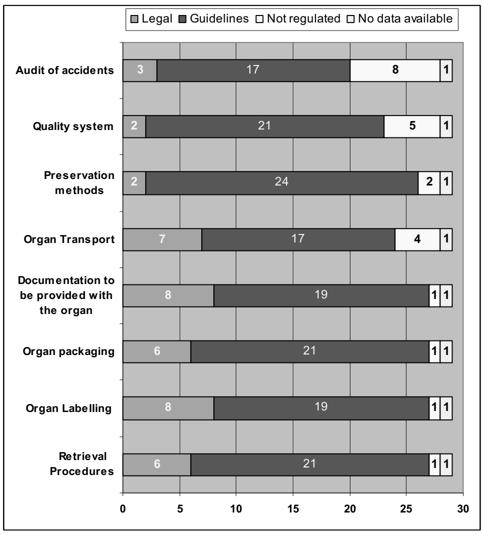
undertaken according to SOPs within a quality assurance programme and should include an appropriate risk assessment.7

The procurement team should provide a sufficient amount of preservation solution. The solutions should be specified in SOPs and comply with existing standards. Possible contamination of the preservation fluid should be avoided and these fluids should be monitored with repeated samplings for bacterial culture. The required temperature should be achieved by external cooling, and continuous monitoring of temperature in the environment of the graft should be provided

The removed organs should be flushed with cold preservation fluid. Donor blood should be removed as carefully as possible from the vessels of the organ, while keeping the organ cool in order to slow down its metabolism. Acceptable cold ischemia times should be specified for each type of organ and be kept to the minimum possible, as it is generally agreed that short preservation time correlates with better organ function.

3.1.8. Organ processing and transportation.

Allograft contamination has been described during processing of organs for transplantation. It also important to ensure that there is effective transportation of organs which minimises ischemic times and avoids organ damage. While maintaining medical confidentiality the organ container must be clearly labelled and should contain the necessary documentation. Next figure shows how different procedures for the retrieval of the organs, their packaging, labelling, preservation and transport, as well as how the documentation to be provided with the organ, the quality systems and the audit of accidents are regulated in the EU. It is clear that in the majority of countries (bars represent countries) these procedures are governed by technical guidelines:



3.1.9. Transplantation programmes

It has been recognised by the experts of the Venice Conference that the recipient preparation, transplant procedure and follow up are critical for the outcome. Transplant procedures should be performed according to the state of the art, only in units which have all the necessary

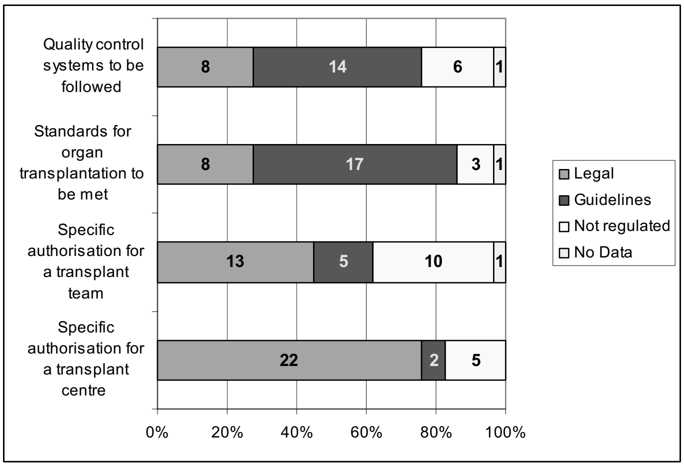
7 Guide to safety and quality assurance for organs, tissues and cells. Council of Europe

facilities and human resources to maximise the safety of the recipient. The staff involved should have appropriate training and experience.

The authorization of establishments and programmes of organ transplantation has been identified as one of the key elements to ensure quality and safety. The Council of Europe recommendation Rec (2004)19 of the Committee of Ministers adopted on 15 December 2004 (6) recommends that that the governments of its member states take all necessary measures to ensure that criteria for the authorisation of organ transplantation facilities were in place. The recommendation considered that given that organ exchange and circulation of patients is becoming a more frequent phenomenon, minimum common standards should be guaranteed to the citizens.

The conclusions of the Venice conference also stressed that the evaluation of procedures and outcomes is critical to the safety and effectiveness of transplant services. Transplant services should submit evaluation data to appropriate registers. Member States should take appropriate measures to ensure that a system is in place for collecting and analysing transplant follow up data on a regular basis.

The following figures show the requirements in the different countries in relation with authorisation of organ transplantation. The bars indicate the number of countries.



3.1.10. Traceability and vigilance of adverse events and reactions

It is important to ensure that all transplanted material can be traced forward to recipients and back to the donor. It is mandatory to inform the relevant contacts of donors or other recipients about potential problems coming to light after transplantation, when relevant to their health

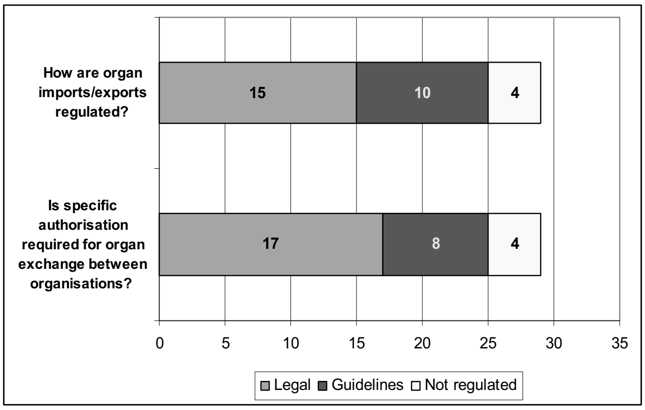
Twenty-five of the countries surveyed have a national register containing data on the origin and destination of the organs; in 18 of these countries this register is legally binding. From the countries where a register is in place, 15 have binding rules on restricted access and confidentiality. The percentage of countries with registers in place in the different settings (procurement sites and transplantation centres) is also indicated in figure below.

It is necessary that national organizations ensure that specimens of serum and mononuclear cells of the donors are stored and can be reanalysed afterwards. Registers of activities in the procurement centres or in transplantation centres are only required by law in few Member states. Only five Member States require banking of serum samples for each donor.

Only in 8 countries is there a binding official mechanism for reporting of serious adverse events. In 12 more the system is driven by guidelines. This of especial interest as already mentioned every year, a number of organs are exchanged between EU Member States.

3.1.11. Import / exports

The regulation of the authorisation of organ imports and export from or to third counties are not regulated in many European Member States. The bars indicate the number of countries. These could have implications on the trafficking of organs in the Community



3.2. Organ Shortage

The severe shortage of organ donors remains the main challenge that Member States in the European Union face with regard to organ transplantation. This section identifies the main facts and causes of this problem.

3.2.1. Growing waiting lists

It is a fact that more than 40,000 patients are currently waiting for a kidney in Western Europe. Waiting lists have increased in all EU countries and in the rest of countries of the world.

Even in cases of sustained increases in the number of donors', waiting list patients and times are very difficult to reduce. Demand of transplant increases more and faster than organ donor rates. However, the increase in the number of available donors will help to reduce the gap between supply and demand if not getting an absolute reduction of the waiting list.

Average prevalence rate of end stage renal failure in Europe is around 1,000 patients p.m.p. Among those, between 20 and 30% are accepted to the waiting list for a kidney transplant. Annual incidence is around 140-150 new patients p.m.p., giving an average need of kidney transplants of 50 grafts p.m.p. per year, to cover the yearly needs. This rate will stabilize the waiting list but not decrease it, since the historical will always remain. Kidney transplant rates over 60 p.m.p. are necessary to reduce both renal waiting patients and waiting times. An increase in the organ donation rate up to 25 donors p.m.p. which is feasible and achievable will not be enough, but more easily complemented with other alternatives such as living donation.

Austria	826	Greece	775	Poland	1105
Bulgary	36	Hungary	939	Portugal	
Belgium	955	Iceland		Romania	1512
Czech. Republic	343	Ireland		Slovak Republic	741
Cyprus		Italy	8688	Slovenia	81
Denmark	384	Latvia	354	Spain	4152
Estonia	29	Lithuania	434	Sweden	503
Finland	272	Luxembourg	11	The Netherlands	1088
France	5932	Malta		United Kingdom	7126
Germany	8853	Norway	174	TOTAL	45313

Table 1. Patients awaiting for a Kidney transplant by 2005; 31st December[8]

3.2.2. Increased demand of transplants

The excellent results of transplants during the last decade, in terms of life years gained and improvement of quality of life, has multiplied the indications of these therapies. The tables below show the evolution of the patients admitted to the waiting list and the number of kidney grafted (table 2) and liver (table 3) transplants, in some European countries. It shows how the number of patients admitted to waiting lists has increased much more than the transplants performed.

[8] Data from the Newsletter Transplant. Council of Europe- 2005

	1989		2004			
	Waiting list	Transplants	Waiting list	Evolution %	Transplants	Evolution %
France	4.603	1957	5.380	16,8	2.127	8,6
Eurotransplant	9.445	3.172	12.251	29,7	3.948	24,4
Skandiatransplant	926	854	1.235	33,3	927	8,3
U.K. /Ireland	3.704	1.960	6.829	84	1.924	-1,8
Spain	5.024	1.039	4.026	-19,8	2.133	105

Table 1. Kidney Transplants and Waiting List Patients

	1989		2004			
	Waiting list	Transplants	Waiting list	Evolution %	Transplants	Evolution %
France	183	585	460	151	833	42
Eurotransplant	180	499	2.035	1000	1.391	178
Skandiatransplant	21	65	58	176	248	281
U.K. /Ireland	51	298	271	431	665	123
Spain	90	170	631	600	1037	501

Table 2. Liver Transplants and Waiting List Patients

3.2.3. Limited donor pool

It is also clear that the need for transplants increases much more than the available organs. There are different reasons for the shortage of donors. The majority (more than 90%) of the organ donors are patients who died in hospitals after an irreversible cessation of all brain functions, known as brain death. These patients are in Intensive Care Units where their cardio-respiratory functions are artificially preserved. Less then 3% of the deaths in hospitals are diagnosed with brain related criteria before cardiac arrest, and therefore the number of potential organ donors is low.

There are other two other parallel groups of donors: firstly living donors (donors of single kidney or undergoing hemi-hepactectomy) and the so call non-heart beating donors, these are patients in irreversible cardio circulatory arrest with a warm ischaemia time reduced enough to allow the extraction of the organ suitable for transplant. NHBD are defined in four categories after the Maastricht Workshop in 2005 (Masstricht riteria). However the use of these types of donors have not been actively actively favoured in many Member states given its ethical implications.

3.2.4. Variability in Donation rates from deceased donors

Linked with the limited donor pool it is the fact that there are important differences in the deceased organ donor rate within the EU. These differences cannot be explained only by differences in the general or specific mortality rates.

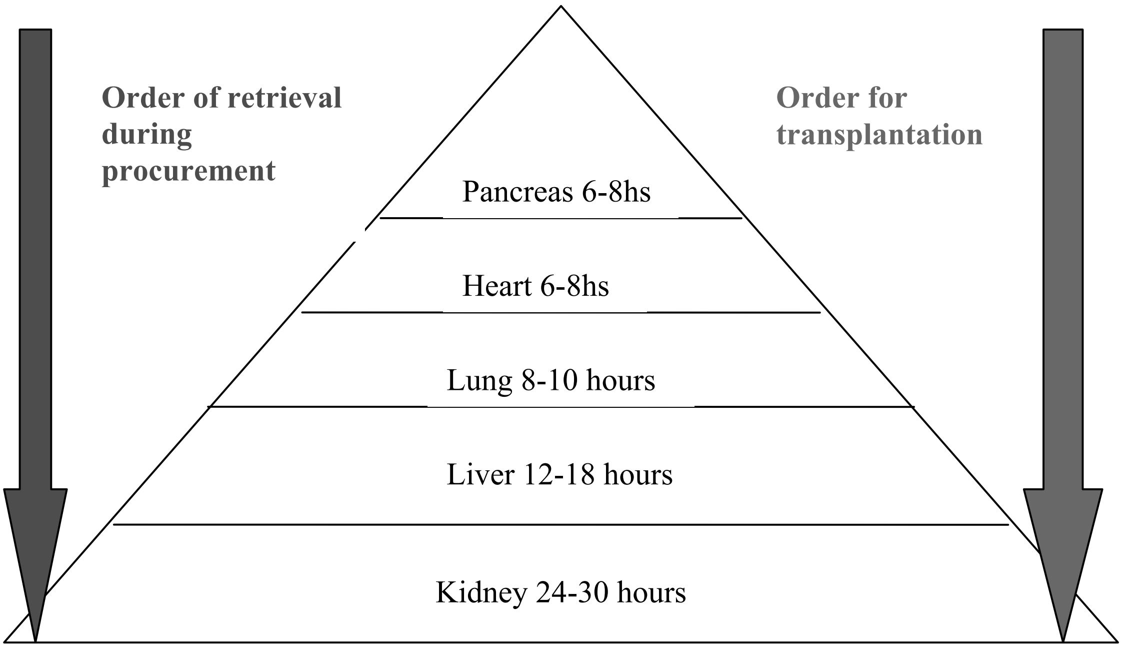
Austria	24.8	Greece	8.1	Poland	14,5
Bulgary	0,8	Hungary	18	Portugal	19
Belgium	23.8	Iceland	6.8	Romania	0,5
Czech. Republic	20,3	Ireland	17.6	Slovak Republic	12.1

Cyprus	8.9	Italy	21	Slovenia	10.5
Denmark	11,9	Latvia	20	Spain	35.1
Estonia	26.9	Lithuania	10,2	Sweden	14.2
Finland	16.2	Luxembourg	6	The Netherlands	14.6
France	22.2	Malta	10	United Kingdom	12.8
Germany	14.8	Norway	16.5		

Table 4. Organ donor rates (per million population (p.m.p.). 2005[9]

3.2.5. Ischemia times.

In addition organ transplants are subject to time pressure. The process from the procurement to the transplantation should be done in a few hours (in order to preserve the organ viability. Safety and quality evaluation procedures will take those differences into account.



3.2.6. Compatibility donor recipient

In order for organs to be transplanted, the donor has to match with the recipient. In organ transplants ABO (blood type) matching is required, although in some situations can be overridden. Good HLA (human leukocyte antigens) matching between donor and recipient is usually desirable for renal, pancreatic and small bowel transplants, but may not be required for other organ transplants. For thoracic and liver transplant recipients, a match in body size is an important consideration. Paediatric organs should preferably be offered to paediatric recipients.

[9] Data from the Newsletter Transplant. Council of Europe- 2005

3.2.7. Organisational complexity

All explained above makes the organisational structure key in the organ donation/transplantation systems. It has an important role in the quality and safety of organs and also in their availability. The Donation / Transplantation process is complex involving many different steps; each transplant can require many professionals and more than 20 hours of continuous work. The process starts with the identification of the donors. After a careful evaluation in the search for any contraindication representing a potential risk for the recipient, all potential donors will be identified. After that comes the necessary clinical and legal certification. In case of deceased donor during all this time the haemodynamic stability must necessarily be maintained to preserve the viability of the organs.

In the case of the legal or social requirement of the family consent (the case in most countries), It is needed to approach the relatives and interview them to request consent. The necessary arrangements, both within and outside the hospital, for multiple organ retrieval must also be made. The organs should be shared according to the previously approved allocation criteria, and the coordinating office should provide a complete logistic support. Once the retrieval is finished the organs will be grafted.

The distribution and exchange of organs must be organised in such a way as to distribute them as ethically as possible, facilitating a policy of exchanges, maximising the benefit from the organs generated and the recipient chances of a transplant. All this implies more management standards in waiting lists and more consensus-based distribution or allocation criteria. During this process a number of preservation solutions are used and the organ has to be maintained in cold temperature

3.2.8. Ethical issues

There are many complex and sensitive ethical issues in this area that have could have repercussion on the availability, and it became clear that several of these aspects are dealt differently in Member States. It is generally accepted that the donation should be voluntary and altruistic with legal and ethical contexts clearly defined, the data from donors and recipients should be protected, provided that traceability is ensured, except in the case of a living donor with a close relationship to the recipient.

Most of the Member States that responded to the Commission survey2 have legislation to protect the donor in respect of anonymity (measures ensuring that the identity of the recipient(s) is not disclosed to the donor or his family and vice versa); confidentiality (measures ensuring that all data collated, including genetic information, have been rendered anonymous so that the donor and the recipient are no longer identifiable) and non remuneration for the donation (measures preventing organ trade or trafficking).

There is a general agreement that cadaveric organ retrieval is only allowed if some form of consent is available from the deceased or his relatives. This is also reflected in international guidelines; according to the additional protocol to the Convention of Biomedicine of the Council of Europe concerning Transplantation of Organs and Tissues of Human Origin10. Member States should ensure that there is a legal basis for ensuring valid consent or objection

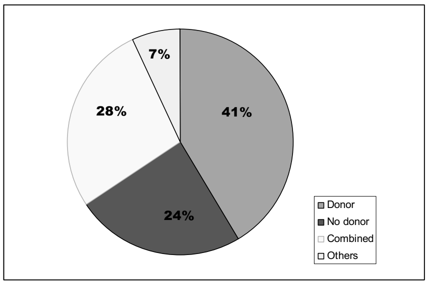
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10 http://conventions.coe.int/Treaty/Commun/QueVoulezVous.asp?NT=186&CM=8&DF=8/29/2006&CL=ENG

to organ donation. The results of the Commission survey showed that in 28 countries the consent for a donation from the deceased donor is embedded in a binding law[2]. Only in one is it organised through guidelines.

Basically two kinds of consent can be distinguished: systems of explicit consent (opting in) and systems of presumed consent (opting out). In the former the donor himself has to authorise organ removal after his death (in the form of an advanced directive or donor card or by filling in a form in order to record consent in a national register). In the latter kind of system, explicit consent is not required: it is sufficient that the deceased donor has not objected during his life (according to national law); in that case consent is presumed.11 It has to be noted that the dichotomy between pure opting in and opting out systems represent an oversimplification that fails to recognise the nuances with which these systems function in practice.

There are mainly four forms of consent found among the countries surveyed. In 8 of the countries consent required always the agreement of those close to the deceased. 7 countries have in place a present consent law, but the family agreement is requested if the wishes of the deceased are unknown, in other 7 countries there are present consent law but in practice the confirmation of the family is needed, and in the rest of the countries surveyed (7) the presumed consent law applies and no family confirmation is needed.An important operational aspect of consent systems (whether explicit or presumed) is the way the consent of objection is being recorded. A growing number of European countries have established national registers so that the information on the willingness to donate is readily available and easily accessible for health professionals confronted with potential donors in a hospital or elsewhere. Most of the countries surveyed2 have a register in place; in 16 the existence of these registers is compulsory by law. There are different types of registers: dedicated registers of donors, non-donors, combined and other types such as a register of inhabitants that incorporates also the information about the willingness – or not - to donate or other kind of registers such as driving license or donor cards.



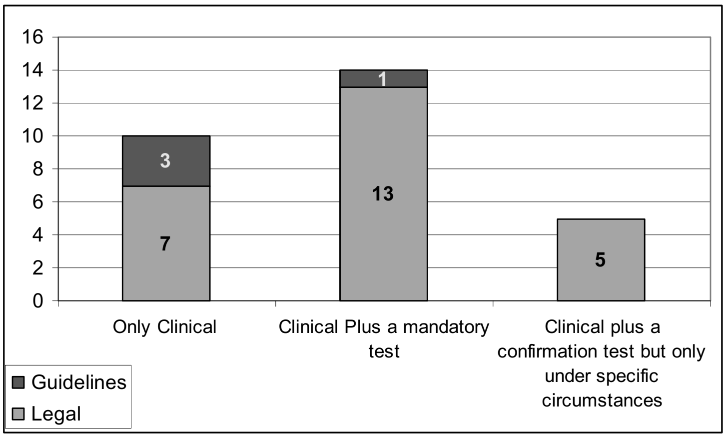
Regarding the consent of the living donor is also regulated by law in most of the countries2

Transparency, Equity and Accessibility – It is also generally accepted that all transplant systems rules (allocation, access to transplant services, activity data, etc.) should be made public and be properly controlled.

Death certification - Organ retrieval from the deceased may take place only after death certification. Death certification should be a matter of national legally binding rules that should be made public.

11 S Gevers, A.Janssen; R. Friele. Consent systems for post mortem Organ donation in Europe. European Journal of Health Law 2004 (11): 175-186

Of the countries surveyed, 86% (25) have binding legislation in place establishing a definition of brain death, three more have technical guidelines with definitions. As to which criteria are needed in the different countries for diagnosing brain death, differences are in evidence as indicated in figure 5 (the bars indicate the number of countries):



The number of doctors that have to confirm brain death also varies between the countries; in 10 two doctors have to sign the certificate, in another 10 the number of doctors needed is three, while 8 countries require only one doctor and in one country four doctors are required.

The situation is different regarding a binding definition of death in non-heart beating donors. Only 45% (13) of the countries have this definition in their legislation and five more in technical guidelines.

3.2.9. Participation of the society

On the other hand, organ donation and transplantation are the only medical treatments that require the participation of society for their full development. One of the main reasons of the shortage of organs is the family refusals to donation. These refusals also vary widely within Europe:

Austria		Greece	46,2	Poland	9,11
Bulgaria	33,3	Hungary	8,6	Portugal	6
Belgium		Iceland	25	Romania	21,4
Czech. Republic		Ireland		Slovak Republic	17,1
Cyprus		Italy	29,4	Slovenia	22
Denmark		Latvia	19,3	Spain	16,8
Estonia	20,8	Lithuania		Sweden	
Finland		Luxembourg		The Netherlands	
France	30,3	Malta		United Kingdom	42
Germany		Norway	33,3		

They could be explained by the wide variability of procedures in the law of donor consent, for living and deceased donors, the different practices on donor registers, and also other important cultural, economic or social factors that influence the perception of the society of the benefit of donation.

In 2006 a survey carried out by the European Commission12 asked to European citizens if they have already discussed within their families the possibility of being organ donors. 58% of the surveyed answered that they never had this discussion and 41% that they have already talked about it. This situation is worse respect the same survey done in 200213

	EB66.2, automne 2006			**EB58.2, printemps 2002**
	UE25	**UE15**	**NEM10**	**UE15**
Oui	**41**	44	25	*46*
Non	**58**	55	73	*52*
Ne sait pas	**1**	1	2	*2*

In the same survey 56% of the answers declared to be ready to donate their organs to an organ donation service after their death, 26% were against this possibility and 18% didn't know or didn't want to answer the question. There were clear differences between Member states as the next figure shows.

[12] Special Eurobarometer December 2006 Organ donation and transplantation

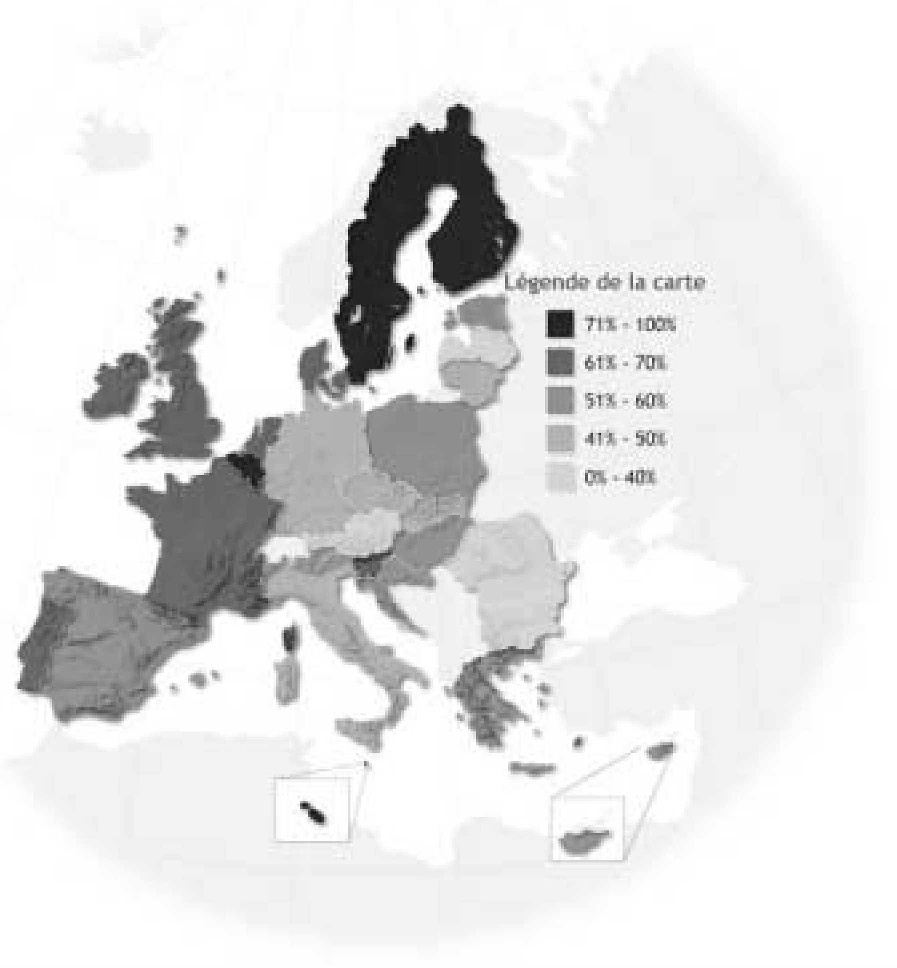
[13] Special Eurobarometer December 2002 Organ donation and transplantation http://ec.europa.eu/health/ph_threats/human_substance/documents/ebs_183.5_fr.pdf

Question: QB36. Seriez-vous prêt(e) à donner un de vos organes à un service de don d'organes tout de suite après votre mort ?

Réponses: Oui

Résultats par pays	
SE	81%
MT	75%
FI	73%
BE	71%
DK	69%
NL	69%
FR	67%
IE	67%
PT	66%
UK	63%
SI	63%
LU	62%
EE	58%
ES	57%
CY	57%
UE25	56%
EL	53%
HU	51%
PL	51%
SK	50%
LT	48%
DE	46%
IT	45%
CZ	44%
AT	33%
LV	29%

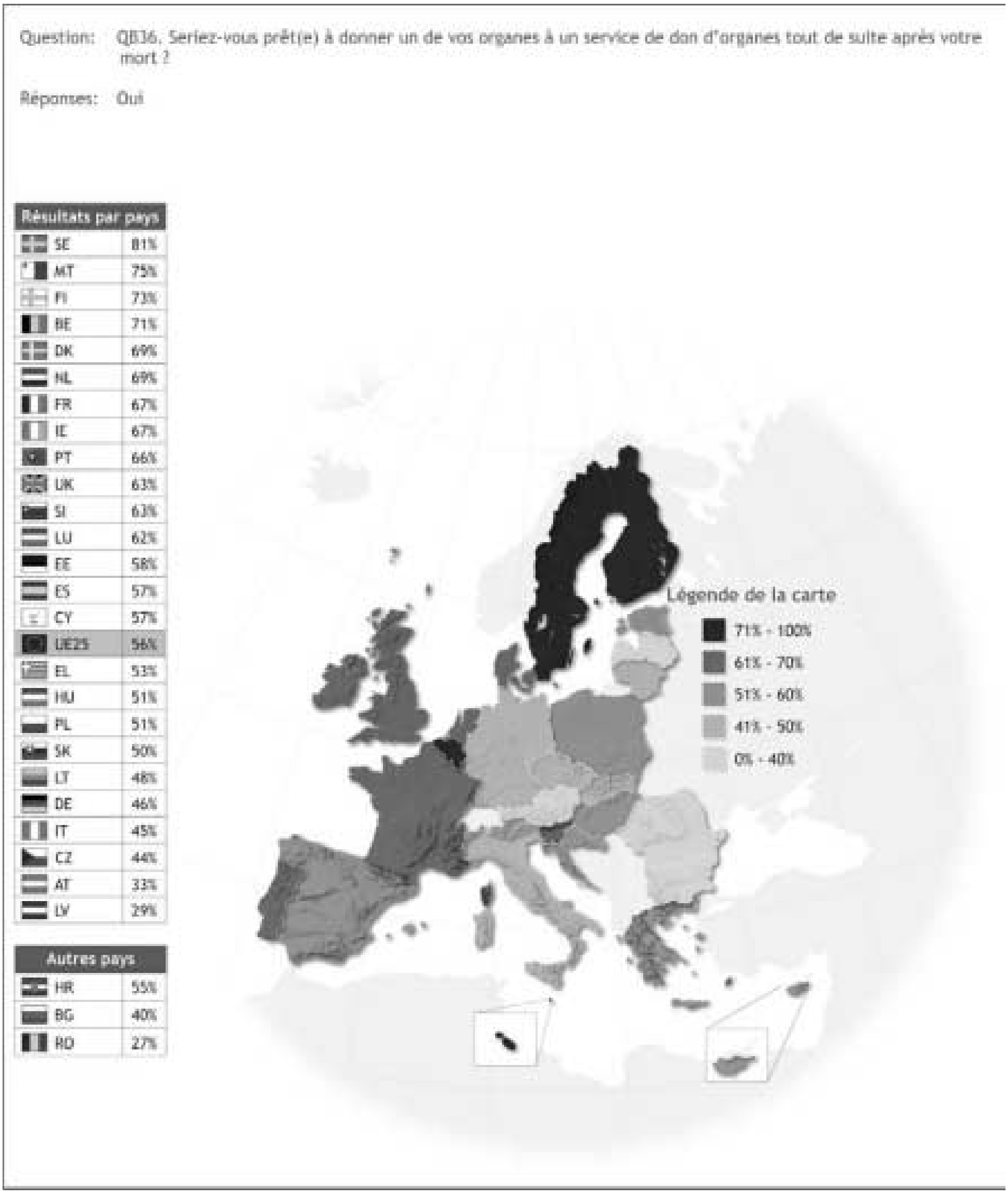
Autres pays	
HR	55%
BG	40%
RO	27%



More precisely the persons less favourable to the donation were people on retirement (49%), those persons with more that 55 years of age (49%) and persons which have finished full time studies before 15 years old (45%). Students (60%), persons that have suited full time at least until 20 years of age (66%) and the executives (67%) are proportionally the more favourable to donate.

54 % of the citizens have answered affirmatively to the question « If you were asked in a hospital to donate an organ from a deceased close family member, would you agree? 23%

have answered negatively and 23% « I don't know ». Answers again widely defer between countries.



The creation of a European organ donor card, as proposed by the European Parliament in the context of the Opinion on first reading of 16 March 2006 on the Commission proposal for a Health and Consumer Protection Programme, could also contribute to increasing public awareness. Data from the eurobarometer survey in 2006 shows that 81 % of European citizens support the use an organ donor card to make it easier to identify people willing to donate

organs after their death. In spite of this only 12% of Europeans have currently an organ donation card.

3.2.10. Alternatives: Increasing the detection of deceased donors and conversion into actual donors

The adequate supply of organs is key for high quality and safe organ transplantations. A number of different alternatives, related to the organisation of donation systems and current practices, could help to reduce the gap between organ supply and demand.

The combination of an efficient system for organ donor identification and detection and procurement has been identified as a key element in increasing the cadaver donation rate in those countries that have not reached their full potential. It has been said that many donors are lost due to a lack of evaluation, a lack of referral or because the option of donation is not presented to the relatives.

Different initiatives have been explored measure correctly the potential for donation in all Member States (DOPKI project) and to increase the conversion rate of potential donors in actual donations in Member States. Since many years, the Donor Action Foundation (DA) has profiled itself as the only international organisation with activities in 10 European countries. DA has organised multiple international, national and regional training courses to familiarize users with its methodology. DA has been able to increase donation rates with 50 to 70% in hospitals, regions and countries that have implemented the DA methodology

In many Member States, the training and employment of health care professionals responsible for detecting potential deceased organ donors and organising the donation process has increased the efficiency of the procurement of organs and improved the functioning of local and national transplant systems. Such professionals can also increase the rate of donation of tissues for transplantation. The Council of Europe has adopted a recommendation regarding the role and training of professionals responsible for organ donation (transplant "donor co-ordinators"). It recommends member States to appoint a professional responsible for the identification of potential deceased organ and/or tissue donors in every hospital with an intensive care unit, the so call "Donor co-ordinators", should have a high standard of professional training consistent with internationally recognised standards, to ensure the highest possible professional and ethical standards in organ donation and procurement.

3.2.11. Alternatives: The use of living donors

The use of living donors is an increasing alternative given the failure to meet the growing need for organs with cadaver donation. Living donation in Europe represents 17% of kidney transplant activity and 5% of liver transplantation. The use of living donors varies widely within Europe, from countries like Spain where they currently account for less that 4% of transplants, and other countries, mainly in Northern Europe and North America where the percentage of living donor transplants represents between 20% and 50% (figure below).

Although living donors have always been critical for transplantation, the use of living donors has dramatically increased over recent years for kidney and portions of liver. The increase in living organ donation can be attributed to multiple factors, including pressure created by the shortage of deceased donors, surgical advances, and strong evidence of favourable transplant outcome and low donor risk.



There is ample evidence from world wide transplant outcome studies, that the short and long term clinical outcome from living related donor kidney transplants are equal to or significantly better that the overall results of kidneys transplanted from deceased organ donors.

Living kidney donor transplantation carries some medical risks for the donor. The mortality risk has been calculated at 1:3000. The risk of a serious, but not life-threatening complications have been estimated to be 1-2%. However, if properly screened, there is very little risk that a donor will suffer any long-term health problems resulting from the unilateral nephrectomy.

DOPKI project has looked into the Regulations in terms of living donation, these always imply a restriction in order to protect the potential living donor or to prevent organ trafficking. Hence it is only consequent that those restrictions are regulated by law since they effect the right of the living donor do decide himself about his physical integrity and it also deprives the living donor recipient from a possibly lifesaving treatment.

In all participating countries in the project organ trafficking is penalized and living donation has to be altruistic.

Generally living organ donation from minors is not accepted however in some countries (UK, Switzerland, Slovenia) exceptions can be made. The principle of subsidiarity - meaning that living donation is only allowed if no post mortem organ is available is only applicable in three countries. The majority of the participating countries require a specially defined relationship between donor and recipient and thus altruistic directed or non directed living donation can not take place in those countries. 10 out of sixteen countries have installed ethical committees that need to approve of the planned donation or require an approval by court.

It goes without saying that in all countries living donation requires an informed consent of the living donor.

3.2.12. Alternatives: The use of marginal donors

In order to increase the pool of available organs for transplantation, donor profile has changed dramatically. In some areas more than 30% of the organ donors are over 60 years old , 20% of them are hypertensive or 6% are diabetic. The so called "expanded or marginal donors" showed that transplantation of those "expanded kidneys" fields a substantial survival advantage over maintenance of dialysis14.

The critical shortage of organs, the morbidity and mortality of patients awaiting transplantation have mandated careful reconsiderations of other potential donors who are not ideal candidates due to positive serology or history of malignancy. Transplantation of livers and kidneys with positive serology for hepatitis B or C into recipients with appropriate serological and viral profile has been accepted by some transplant teams.

The use of organs from donors with malignancies has been not recommended by international bodies15. In less than 1% of all potential donors referred and after the medical examination we discovered the presence of an unknown malignancy during the surgical procedure. In this situation, usually organs are discarded, however several cases affecting very specific tumors in which the graft had already been performed, did not reveal any problem in the follow up. The decision to use or not organs from such donors would be based upon the known biological behaviour of those tumours, always keeping in mind the benefit not only for individuals but also for the entire transplant community. Again, published experience is not enough to establish safety limits in the practice. Same can be said for other hundreds of donors with pathological findings genetic or congenital disorders, or very rare diseases or conditions. Cooperation between countries will give bigger number of recorded charts to be on the way of defining quality and safety practice guidelines for those cases.

An informed consent should be provided by the transplant candidate, unless their physical or mental condition does not allow them to do so.

DOPKI project has started to search into the different regulations in the participants countries. The table at the end of this section shows whether regulations on expanded donors are existent within each country and if yes what its contents are.

3.2.13. Alternatives: The use of non-heart beating donors

As already mentioned there is recent evidence that developments in the screening of seriously ill patients and changes in intensive-care practices may lead to fewer patients dying in an intensive care unit and meeting the criteria for determination of brain death. In order to expand the donor pool it is important to consider donations from non-heart-beating donors (NHBD). These are donors who have suffered a cardio-respiratory arrest in which special cooling and preservation techniques can be established in a very short period of time (generally less than thirty minutes), although the blood flow has not been maintained

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[14] B. Miranda, J. Vilardell., JM: Grinyó. Optimizing cadaver organ procurement. The Catalan and the Spanish experience. Am.J.Transpl. 2003; 3:1-8

[15] International Consensus Document Standardization of Organ Donor Screening to Prevent Transmission on Neoplastic Diseases. Council of Europe Newsletter Transplant. September 2001;Vol.6.N'1:45-51.

permanently by a machine, under certain circumstances these people could be donors of certain organs).

The DOPKI project has investigate the situation on non heart beating donors in several European Countries. In four out of 16 countries – namely in Croatia, Germany, Hungary, and Poland NHBD is legally not permitted since a completed brain death diagnosis is required prior to organ retrieval.

Apparently in some countries there are no legal restrictions however respective programs have not been installed. In Italy, Portugal and France – even though NHBD is not forbidden from a legal point of view, programs are not existent or only recently under development.

From the 14 countries where non Heart beating donation is allowed by law only UK allows donation in all categories and has also programs in place in each category.

Non Heartbeating Donation										
Organisation	**Country**	**NHBD legally approved?**	**Maastricht Category I**		**Maastricht Category II**		**Maastricht Category III.**		**Maastricht Category IV.**	
			Legally approved	Existing programs	Legally approved	Existing programs	Legally approved	Existing programs	Legally approved	Existing programs
./.	Austria	Yes *	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Belgian Transplantation Society (BTS)	Belgium	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
MZSS	Croatia	No	No	No	No	No	No	No	No	No
KST	Czech Republic	Yes	Yes	Yes	Yes	Yes	No	Yes	No	No
ABM	France	Yes	Yes	Under development	Yes	Under development	No	No	Yes	Under development
DSO	Germany	No	No	No	No	No	No	No	Yes, if brain death diagnosis completed	No
Hu-T	Hungary	No	No	No	No	No	No	No	Yes, if brain death diagnosis completed	
CNT	Italy	Yes	Yes	No	Yes	No	Yes	No	Yes	No
./.	Luxembourg	NO	No	No	No	No	No	No	No	No
NTS	Netherlands	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
Poltransplant	Poland	No	No	No	No	No	No	No	Yes	No
OPT	Portugal	Yes	Yes	No	Yes	No	Yes	No	Yes	No
Slovenija-Transplant	Slovenia	Yes	Yes	No	Yes	No	Yes	No	Yes	Yes
ONT	Spain	Yes	Yes	Yes	Yes	Yes	No	No	Yes	Yes
Swisstransplant	Switzerland	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
UK - Transplant	United Kigdom	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes

* law says: ..removal of organs of deceased people.. Not specifically brain death or cardiac death

TABLES FROM DOPKI PROJECT

Living Donation										
Organisation	**Country**	**Regulated by Law (In parliamentary Transplantation act)**	**Informed Consent required**	**Allowed for Minors/persons lacking legal capacity**	**Principle of Subsidiarity**	**Requirement for Donor-recipient-Relationship**	**Approval by ethical committee**	**Approval by court**	**Altruistic/No remuneration**	**Organ trafficking penalized**
./.	Austria	No; only position paper	Yes	No		No	No	No	Yes	Yes
BTS	Belgium	Yes	Yes	No		No	Not mandatory	No	Yes	Yes
MZSS	Croatia	Yes	Yes	No		No	Yes		Yes	Yes
KST	Czech Republic	Yes	Yes	Yes		Yes	Yes	No	Yes	Yes
ABM	France	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes
DSO	Germany	Yes	Yes	No	Yes	Yes	Yes	No	Yes	Yes
Hu-T	Hungary	Yes	Yes	No	No	Yes	Yes	No	Yes	Yes
CNT	Italy	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes
./.	Luxembourg	Yes	Yes	No		Yes	No	No	Yes	Yes
NTS	Netherlands	Yes	Yes	No		No	No	No	Yes	Yes
Poltransplant	Poland	Yes	Yes	No	No	Yes		Only in case of non relatives	Yes	Yes
OPT	Portugal	Yes	Yes	No	Yes	Yes	Yes	No	Yes	yes
Slovenija-Transplant	Slovenia	Yes	Yes	Yes,with obligations		Yes	Yes	Yes	Yes	Yes
ONT	Spain		Yes	No	Yes	No	Yes	Yes	Yes	Yes
Swisstransplant	Switzerland	from 2007	Yes	Yes, with some obligations		No	Yes	Yes	Yes	Yes
UK - Transplant	United Kigdom	Yes	Yes	Yes, rare	No	No	Yes, from 1 September 2006 all living donations will be approved by the Human Tissue Authority.	Yes	Yes	Yes

Extended Criteria Donor							
Organisation	Country	Do regulations exist defining ECD and their utilisation?	Age limits for Donors? If Yes, what age?				
			Kidney	Liver	Heart	Lung	Pancreas
	Austria	Not regulated.					
BTS	Belgium	No, age relative contra indications are set down in Eurotransplant manual.	no	no	no	no	no
MZSS	Croatia	Yes, regulations exist. They are also established by The ordinance on measures to assure the safety and quality of parts of the human body for medical use (consistently with "Guide to safety and quality assurance for organs, tissues and cells" from The Council of Europe, see attachment!!!), and by National guidelines for treatment, allocation and preparing of potential patients for kidney transplantation					
KST	Czech Republic	Not regulated.					
ABM	France	There is one protocol on double kidney transplantation; There is specific rules for organs harvested in a donor positive for HCV or HbV and syphilis	No	No	No	No	No
DSO	Germany	Criteria for allocation limitations:Organs from donors with grave prior diseases (e.g. history of malignancy) or complications resulting from these diseases require a special allocation procedure.For example expanded donor criteria are given when the donor suffered of one of the following diseases:- viral hepatitis (alternatively HBS Ag+, anti-HBC+ or anti-HCV+)- sepsis with positive blood-culture- malignant tumour in medical history- drug abuse. Specified criteria for extended donor criteria are only existent for liver transplantation such as (alternatively): - Age of donor > 65 years- ICU-treatment including artificial respiration > 7 days- donor adipositas >BMI.>30- fatty liver (histologically affirmed) > 40 %- Sodium>165mmol/l - SGOT or SGPT >3x average (last parameter before notification as donor) or- S-Bilirubin >3mg/dl (last parameter before notification as donor) Each individual case has to be evaluated by the physicians involved in the organ retrieval in order to determine whether the extended donor criteria are fulfilled or not. Different allocation mechanism according to centre and patient profile	No	No	No	No	No
Hu-T	Hungary	Not regulated. Donor criteria are summarized in guidelines.	No	No	No	No	No
CNT	Italy	YES, national guidelines exist for safety and give allocation limitations - There is no age limit that needs to be followed by coordinators but transplant teams are free to decide case by case	No	No	No	No	No
./.	Luxembourg	No	No	No	No	No	No
NTS	Netherlands	YES, non-heartbeating donation, EurotransplantSeniorProgram (old for old)	No	No	No	No	No
Poltransplant	Poland	There are also such guidelines issued in Poltransplant's Manual. They are organ specific and are different depending on the organ retrieved. The English version is not readily available	No	Yes, 60	Yes, 60	Yes, 60	Yes, > 50 and < 5
OPT	Portugal	No	Yes,	No	Yes	Yes	Yes
Slovenija-Transplant	Slovenia	There are guidelines in the Sloveniatransplant manual	No	No	No	No	No
ONT	Spain	Organ Specific guidelines	No	No	Yes, < 60	Yes, < 60	Yes, < 55
Swisstransplant	Switzerland	Included in the kidney allocation rules, we speak there about handicap kidneys, the recipients have to sign a consent form for a marginal organ	No	no	no	no	no
UK - Transplant	United Kigdom	No - risk/benefit assessed by local teams	No	No	No	No	No

Table from DOPKI project.

3.3. Organisational Systems

1.Organisational structures have not only an impact on quality and safety of organs but also on the detection, referral and hence the availability of organs. The organizational structure is key in the organ donation/transplantation systems. There is a need for a well organized and effective transplant system. This system needs an appropriate legal framework, a good technical approach and organizational support.

The DOPKI project has evaluated these organisational systems in many European Countries: As can be seen in the Table (From DOPKI project) below all participating organisations are in charge of the coordination of organ donation. Only a very small percentage of countries that have installed a national organ procurement agency are not in charge at the same time for organs and tissues. These results coincide with those from the Commision Survey: most of the organ transplantation organisations are also in charge of the activities of human tissues (82% of them) and in a low percentage (57%) they also deal with haematopoietic progenitors.

Field of Activity					
Organisation	**Country**	**Organs**	**Tissues**	**Cells**	**Others**
./.	Austria	./.	./.	./.	./.
BTS	Belgium	Yes	Yes	Yes (but not mentionned in the law 1986)	./.
MZSS	Croatia	Yes	Yes	./.	./.
KST	Czech Republic	Yes	Yes	./.	./.
ABM	France	Yes	Yes	Yes	Assisted reproductive technologies; embryo research; genetic testing
DSO	Germany	Yes	New law pending	./.	./.
Hu-T	Hungary	Yes	./.	./.	./.
CNT	Italy	Yes	Yes	Yes	./.
Luxembourgtransplant	Luxembourg	Yes	Yes	Yes	./.
NTS	Netherlands	Yes	Yes	No	./.
Poltransplant	Poland	Yes	./.	Yes	./.
OPT	Portugal	Yes	Yes	Yes	./.
Slovenija-Transplant	Slovenia	Yes	Yes	Yes	./.
ONT	Spain	Yes	Yes	Yes	./.
Swisstransplant	Switzerland	Yes	./.	Islets	./.
UK - Transplant	United Kigdom	Yes	Yes	./.	./.
ET	Netherlands	Yes	./.	./.	./.

Most of the 29 EU countries surveyed in the Commission survey have a national public body (25) in charge of the organ transplantation / organ exchange. Some countries (3) have also this type of structure decentralised in regional bodies. Others (14) have in addition an international organisation in charge of some of the functions.

The majority of organisations is of public character. In Germany and Switzerland private non profit organisations have been mandated by the Ministry of Health in Germany and by state contract in Switzerland (Netherlands) to coordinate the donation and procurement activities. Most of the organisations have a national headquarter but additionally also a regional structure. An overview is given in table 2 (From DOPKI project)

Table: Field of activity of the organisations participating in this project

Structure						
Organisation	**Country**	**Private**	**Public**	**Supranational**	**National**	**Regional**
./.	Austria	./.	./.	./.	./.	./.
BTS	Belgium	./.	Yes	./.	Yes	./.
MZSS	Croatia	./.	Yes	./.	Yes	./.
KST	Czech Republic	./.	./.	./.	Yes	7 regional
ABM	France	./.	Yes	./.	Yes	6 ABM
DSO	Germany	Yes		./.	Yes	7 DSO-Regions
Hu-T	Hungary	./.	Yes	./.	Yes	4 Regions
CNT	Italy	./.	Yes	./.	Yes	./.
Luxembourg Transplant	Luxembourg	./.	Yes	./.	yes	./.
NTS	Netherlands		Yes	./.	Yes	
Poltransplant	Poland	./.	Yes	./.	Yes	./.
OPT	Portugal	./.	Yes	./.	Yes	GCCOT -5
Slovenija-Transplant	Slovenia	./.	Yes	./.	Yes	./.
ONT	Spain	./.	Yes	./.	Yes	./.
Swisstransplant	Switzerland	Yes		./.	Yes	./.
UK - Transplant	United Kigdom	./.	Yes	Yes	./.	./.
ET	Netherlands	Yes	./.	Yes	./.	./.

One could conclude that. two different models are present in the EU: one consists of law-approved, institutional-centered, national transplant organizations (NTOs) based on the principle of local and regional coordination, whereas the other consists of multinational organ exchange organizations (OEOs) whose main objective it is to allow for adequate donor-recipient matching through international organ sharing. In light of these two different models, the EU transplant geography can be split into two areas: countries with NTOs based on the principle of local and regional coordination - such as Spain, Italy, France, and Portugal - and countries grouped into multinational exchange organizations, such as Eurotransplant (Germany, Austria, Belgium, The Netherlands, Luxembourg, Slovenia, and Croatia) or Scandiatransplant (Denmark, Sweden, Finland, and Norway). Even among those nations that have recently joined the EU, some have opted for a NTO-like model (Poland, Hungary), while other, smaller countries have gathered in an OEO-like fashion (Balttransplant for Estonia, Latvia and Lithuania).

What is really essential to the NTO-like model adopted in Spain, Italy and France and differs from the OEO-model currently working in Central and Northern Europe is a different concept of transplant organization. In a NTO model, transplantation is not simplistically a mere medical discipline, but a complex healthcare process requiring active participation from healthcare professionals, stakeholders and local/regional/central authorities. With the exception of UKTSA (the UK Transplant Service Authority), virtually all major NTOs are centrally-governed, institutional organizations, officially endorsed by public laws and/or bills and in charge of disciplining, monitoring of and planning of all donation and transplantation activities within their borders.

2. In addition there are examples of European organisations are already in place, which proves the need and importance of wider –European- cooperation

The Council of Europe, which groups together 46 countries, including 21 countries from Central and Eastern Europe, has been actively involved in this area. The Committee of Experts on the Organisational Aspects of Co-operation in Organ Transplantation (SP-CTO) was set up following the 3rd Conference of European Health Ministers in Paris in 1987 on the ethical, organisational and legislative aspects of organ transplantation.

The Eurotransplant International Foundation is responsible for the mediation and allocation of organ donation procedures in Austria, Belgium, Germany, Luxembourg, the Netherlands and Slovenia. In this international collaborative framework, the participants are all transplant hospitals, tissue-typing laboratories and hospitals where organ donations take place. The Eurotransplant region numbers well over 118 million inhabitants.

As mentioned previously, every year a number of organs are exchanged between EU Member States. Cross border exchanges imply that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. However the number of organs interchanged between Member States constitutes a low percentage of the total organs used for transplantation. However the establishment of Eurotransplant is perhaps an example of how this situation could change if the adequate organisation is in place, the exchange rate of kidneys between partners countries has ranged from 5% for 6 HLA mismatches to 42.8 % for 0 HLA mismatches (23 % of all transplants with and average exchange rate of 19.7%) over the last five years. (EUROCET D7.2)

Scandiatransplant is a Nordic organ exchange organisation and it covers a population of 24 million inhabitants in five countries. According to the by-laws, the purpose of the Scandiatransplant association is fourfold: (1) Scandiatransplant shall effect the exchange of organs and tissue between the participating transplant centres; (2) It shall operate a database and communicate information from it; (3) It shall contribute to promoting the provision of human organs and tissue for transplantation; (4) It shall support scientific activities. Scandiatransplant was founded in 1969 on the initiative of Nordic pioneers within the organ transplantation field.

Two other organisations can be considered as having international scope: Balttransplant, an NGO operating in Estonia, Latvia and Lithuania, and UK Transplant which scope is extended to UK and Ireland.

On April 2004 the Ministers of Health of Italy, Austria, Cyprus, Czech Republic, Estonia, Hellenic Republic, Hungary, Latvia, Lithuania, Malta, The Netherlands, Poland and Slovak Republic signed the Prague Declaration which declared, among other things, the constitution of the European Transplant Network to be the official intergovernmental organisation of participating countries, designated for mutual cooperation in the field of organ and tissue donation and transplantation. Members of ETN are the new Member States of the EU plus Italy Greece and Austria. The organization is open to any country who would like to join it, and Croatia has applied recently. The organization was founded with the aim of establishing close collaboration and exchange of experience among the members in different aspects of the sector for achieving higher standards of efficiency of the involved organizations, which so far present different levels of development.

Finally the main European organ exchange organisations (EOEOs) (Eurotransplant, Swiss transplant, Italian Transplant Centre, Hungaro transplant, UK Transplant, Organização Portuguesa de Transplantação, Etablissement Français des Greffes, Skandiatransplant, Poltransplant, Greek transplant organisation and the Spanish Organización Nacional de Transplantes,) meet on a regular basis. These organisations have already stressed the need to analyse the differences between the EU countries in the accreditation / authorisation / licensing / registration systems (training of professionals, authorisation of centres and transplant programmes, import/export…etc) and the consequences of these differences in the availability of organs and their quality and safety.

3.Even among EU countries with well-developed services, there are considerable differences in organ donation and transplantation activity and it seems that some organisational models are performing better than others. In some countries the transplantation activity exceeds 80 transplanted organs pmp, compared to others with a rate of 40 pmp, and these differences are not necessarily explained by the donation rates. As a matter of example the next figure shows the European activity on liver transplantation in 2005 (data from the Council of Europe).



The DOPKI project is looking into the different performances of transplant systems of the countries participating in the project as it seems that the way transplant procedures are carried out vary between member states; e.g. in some countries the rate of non- renal transplanted organs exceeds the number of kidney transplants, whereas at the other extreme the rate of all other organs is only 20% of the kidney transplant rate. These differences can not be explained by the incidence of the major causes of death or the incidence of end organ failure in the population.. As two examples taken from the current work of the project it has studied the differences between countries of the percentage of multi organ donors. Multiorgan donation should be encouraged and realized whenever possible. Some statistics indicate that this is often not done.

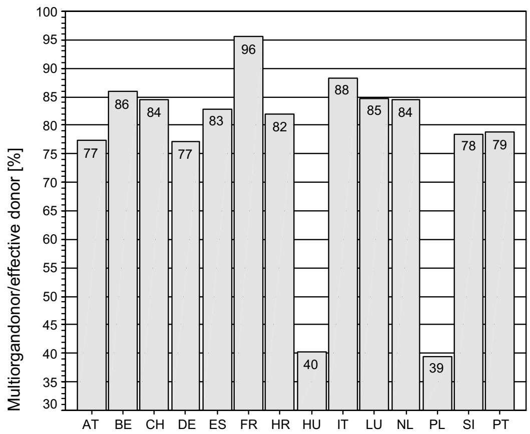
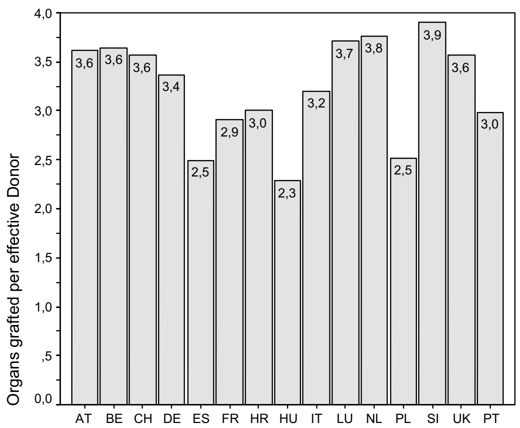


Figure14: Percentage of multi organ donors out of effective donors across countries (mean 2003-2005)

In 12 of the 14 countries studied, the percentage of multi organ donation is around 80 %. Multi organ donation requires that at least two different types of solid organs have been retrieved for transplantation purposes. Another type of efficiency rate studied is to determine how many organs where grafted per effective donor on the average. In 11 out of 15 countries that made this data available to us more than 3 organs where grafted per effective donor.



Number of organs per effective donor across countries (mean 2003-2005)

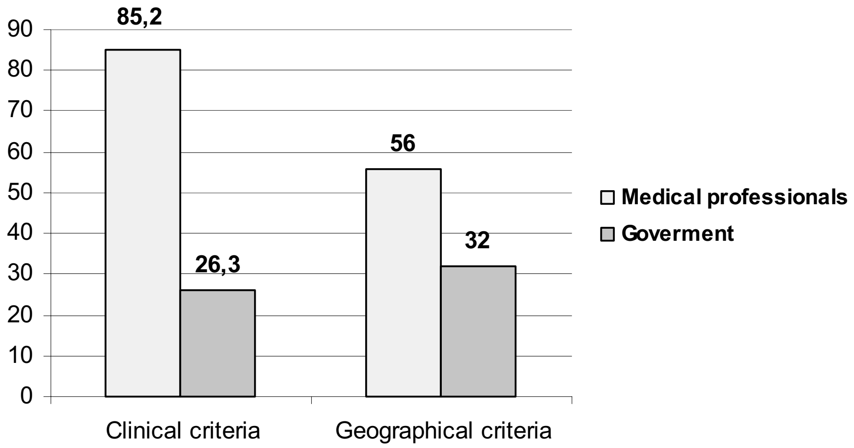
Also the number of transplant centres per population differs widely. For example, the number of liver transplantation centres vary from more that 0.5 centres per million of population in Belgium to less that 0.1 in Hungary or no centres in some Member States. That should be considered given the relation between the accessibility to organ transplantation and the donation rates.

	Number of transplant programs to date 31.12.2005						
Countries	**KIDNEY**	**LIVER**	**HEART**	**LUNG**	**PANCREAS**	**BOWEL**	**TOTAL**
Austria	5	3	3	3	3	0	17
Belgium	8	6	7	4	7	0	32
Croatia							
Germany	42	25	26	15	25	4	141

Spain	42	23	17	7	11	3	104
France	44	24	26	15	14	4	127
HR	4	1	1	0	2	0	7
Hungary	4	1	1	0	2	0	8
Italy	40	21	19	12	15	3	110
Luxembourg	1	0	0	0	0	0	1
Netherlands	9	3	3	3	2	0	20
Poland	18	6	2	3	4	0	33
Switzerland	1	1	1	0	0	0	3
United Kingdom	26	7	7	6	9	3	58
Cech Republic							
Portugal	8	3	4	1	1	0	17

4. As part of this organisation, an effective allocation system is essential. This system has to take into account the short time that organs can be maintained in good conditions prior to transplantation, and the necessity to ensure that the organ is assigned to the most suitable recipient, according to predefined criteria.

In 17 of the countries surveyed2, the allocation criteria for organs are legally binding. These allocation criteria normally refer to clinical criteria (medical situation of the recipient, compatibility, time in the waiting list) and geographical criteria (to reduce the time of ischemia and the efficiency of the process).

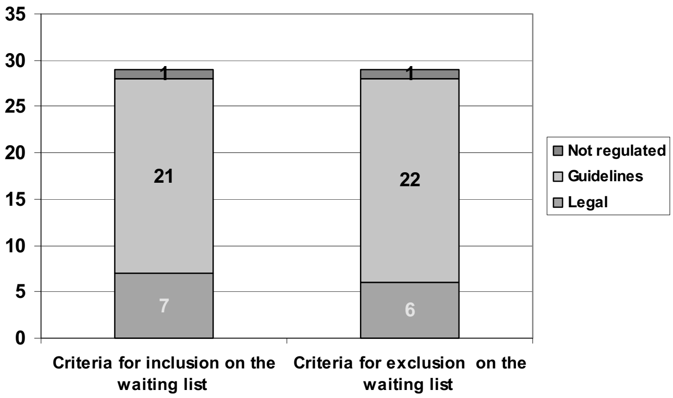


The majority of the countries where information is available (we do not have information on this in 10 countries) use a combination of these two types (12 countries). In five countries the criteria are only clinical and in two only geographical criteria are used. The responsibility of establishing the allocation criteria is distributed as indicated above (percentage of countries).

These criteria are public in most of the countries (26) 2 (in one country data are not available). Also in most of the countries the organ transplantation organisation is responsible for monitoring compliance with these criteria (26). Changes in the allocation criteria are permitted in most of the countries (21), these changes are based in 72% of the countries on the

probability of the transplant for different groups of patients (depending in the age, blood group, place at resident, etc…).

The inclusion and exclusion criteria for waiting lists are governed mainly through technical guidelines, with only few countries having binding criteria2, as is shown below



3.4. Rational for EU action

In areas which do not fall within its exclusive competence, the EU may only act if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States and can therefore, by reason of the scale or effects of the proposed action, be better achieved by the Community (article 5 EC Treaty). This principle of subsidiarity has been invoked frequently in relation to initiatives on health care provision and financing.

The Treaty itself in its art. 152.4 a) provides expressly the possibility for the EC to adopt harmonising measures to ensure Organ safety and quality of organs. National legislations differ between Member States. A national approach could not ensure the same minimum standard of quality and safety for organs.

Organ interchange is already taken place in Europe. In the Eurotransplant area the average exchange rate of kidneys between partners countries was around 20% over the last five years. The Eurotransplant region covers 118 million inhabitants. Common quality and safety rules are needed in this context.

The example of Eurotransplant shows that once a common organisation and common rules are in place, the number of organ exchange increases and contributes to maximize the opportunity for patients to obtain the best possible organ. It also contributes to avoid that potential donors are not considered because the lack of suitable recipient at that moment in the national waiting list.

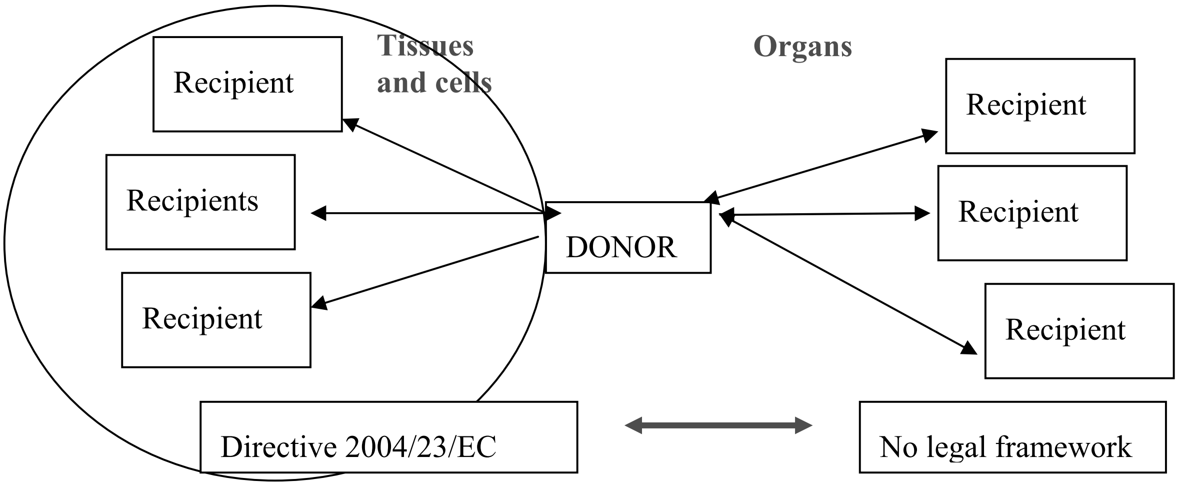
There was identified the need to develop systems for offering exchange of organs for urgent patients and difficult recipients (e.g. children, highly sensitized patients). These patients can not be adequately treated in small member states with limited donor pool, and can clearly benefit from an EU initiative. In order to establish such a system common quality and safety standards should be in place.

Also the movement of donors should be considered (e.g. In Spain close to 10 % of the donors last year were foreigners (more than 50% of these were Europeans) and this tendency has

steadily increased in the last years from 2 % in 2000. Cooperation to introduce initiatives that facilitate information to citizens about the different donation systems in Europe and facilitate these donations of foreign citizens will have an added value.

The exchange of organs is not the only "European issues" that justifies a common set of basic standards, also the movement of patients. Having common binding standards of quality and safety will be the only mechanism to ensure a high level of health protection all along the EU.

It is also important to consider the link with the quality and safety requirements for tissues and cells. Many times an organ donor is also a tissue donor. Currently the Directive on quality and safety covers the traceability and the Tissue and cells adverse event/reaction reporting but not the organ side. These systems should be linked, even if organs are not largely cross border exchanged, tissues and cells are. An adverse reaction in an organ donor recipient should be traced and reported on the tissue vigilance system (already foreseen under the tissues and cells directive) if needed.



This is in close relation to the fact that organ shortage is a common dilemma in all European countries, and that sharing of best practices, best models and expertise across the EU members has already proved useful in increasing organ donor rates in some countries.

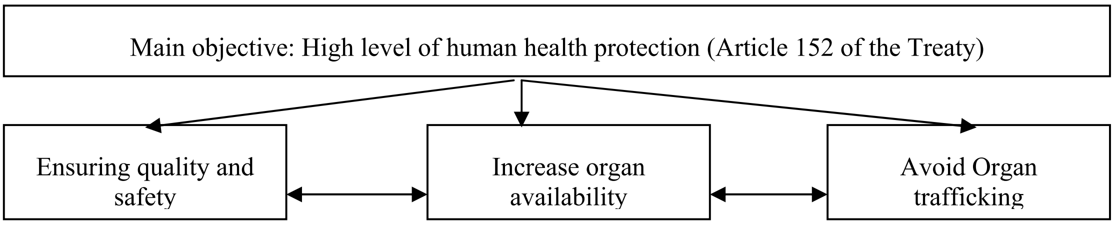
This is of particular interest because the experience shows how some organisational models are performing clearly better than others. Identifying those elements in the different systems (appropriate legal framework, good technical approach or organizational support) that could be promoted at community level will bring a clear European added value, in particular for those member states with less developed systems.

In addition European cooperation is imperative on the evaluation of measures intended to increase organ donation such the use of the so call expanded donors. Again, published experience is not enough to establish safety limits in this practice. Same can be said for other hundreds of donors with pathological findings genetic or congenital disorders, or very rare diseases or conditions. Cooperation between countries will give bigger number of recorded charts to be on the way of defining quality and safety practice guidelines for those cases. This is linked to the need of develop of consensus guidelines and professional standards to ensure good medical practices or the evaluation of post transplant results “organovigilance” to lead to a safer and more effective use of organ donors. This can be addressed more efficiently with a community perspective.

4. OBJECTIVES

In response to the issues outlined in the previous section, the general objective of the EU The main objective of the EU is to ensure high standards of quality and safety for human organs used in therapy at Community level as reflected in Article 152 of the Treaty. This overall objective should be linked to specific objectives related to the main problem identified by the experts in this area, the shortage of organ donors. In order to address adequately the quality and safety aspects an integrated approach is needed, therefore it will be equally important to analyse actions at EU level to increase the availability of organs use in therapy and to promote the accessibility to these therapies in the Community.

The main objectives are represented in the figure below:



Ensuring quality and safety and increasing organ availability are the two main goals of the proposal and should not be addressed separately. Quality and safety is in the core of the Treaty (Article 152). Actions on quality and safety could have an effect on organ availability. There is an important trade-off to consider in this respect.

On the other hand, the availability has also impact on the quality and safety. Maximising the donor pool will allow to select the best organ for the patient in need.

Avoiding organ trafficking is important because any criminal on ethically doubtful activity in this area would undermine the trust of the population of the donation-transplantation process. A loss of trust can seriously lower the donation rates. Ilegal trafficking could also undermine the quality and safety of the process. In the other hand organ trafficking is a consequence of the scarcity of organs, actions oriented to increase organ availability will help to combat organ trafficking.

The operative objectives are detailed in section 7.3.1.

5. POLICY OPTIONS

In June this year DG SANCO launched an open consultation on organ donation and transplantation. The aim of the consultation was to identify the main problems encountered in organ donation and transplantation, to invite ideas on EU initiatives that could help to solve these problems, and to determine the extent to which measures should be taken at Community level.

In the consultation, 3 possible scenarios were outlined for future EU action with regard to organ donation and transplantation:

- To maintain the status quo, continuing certain basic projects already being carried out under different EU programmes without any further coordination.

- To establish an EU structure that would promote active coordination between Member States on organ transplantation e.g. establishing guidelines for quality and safety standards; sharing experiences and best practice; promoting European registers on transplantation; identifying the main problems at EU-level when it comes to organ exchanges; and reviewing the legal framework on organ trafficking.

- To implement an open method of coordination between Member States in which they would work together on the actions outlined in Point 2 above, while the Commission would consider EU legislation to complement and reinforce these actions. A Directive on quality and safety could be an option, along with legislative proposals against organ trafficking.

a) First level: Further work under existing Community programmes.

This option will mean continuing the current work under the different Community programmes (Public heath, Research, Information Society and Justice, freedom and security) to support this area, without any further coordination.

b) Second level: Active coordination between Member States on organ quality, safety and availability.

Article 152.4 constitutes the legal basis for the EC to adopt common measures to ensure high standards of health and safety of organs. Within this framework, Member States remain responsible for a number of significant issues linked to quality and safety, particularly with respect to the organisation of donation systems and health care.

The use of an open method of coordination, specifically adapted to this concrete field, and as a complement to the legislative framework, will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach will be based, in the first stage at least, on the identification and development of common objectives for which it is agreed that a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

Actions:

Coordination on organ transplantation activities between Member States. These could include

- Identifying standards of quality and safety.

- Putting a system in place to facilitate the transmission of the full donor record -a common basic set of donor data- and other relevant information within Europe.

- Sharing experiences and best practices on establishing efficient systems for organ donor detection and procurement.

- Promotion of on-going training of professionals as a key element in this process.

- The cooperation between countries leading to the compilation of sufficient information will assist in determining the acceptable levels of risk in the use of expanded donors.

Promoting EU registers on transplantation or cooperation between national registers should be one of the priorities.

– International co-operation on the promotion of organ donation is desirable to help increase public awareness, maximise organ donation, and equalise access to transplantation between countries. Governments should actively promote such co-operation.

– Identifying the main problems at EU level for the interchange of organs and patients. Systems for offering excess organs to other countries should be developed and in particular exchange of organs for urgent patients and difficult recipients (children, highly sensitive patients, ect).

– Exchange of patients, reimbursements of costs, common transplant lists, admission criteria, prevention of registration on multiple transplant lists, among other subjects, need discussion.

– Agreeing a common ethics code on organ transplantation.

c) Third level. Second level + Minimum harmonisation on quality and safety + Initiative on Organ trafficking

It could be proposed that this open method of coordination should be implemented for an initial period upon which an evaluation on the need for a Directive on quality and safety is undertaken. After this "phasing in period" and in the light of the evaluation of the implementation of the coordination method, the introduction of additional legislative instruments should be considered. It could also be proposed that the coordination method starts in parallel with the elaboration of legislative instruments. In any case, an impact assessment shall be performed before deciding on the appropriateness to the introduction of additional legislative instruments

This option builds on the previous level. In addition to the actions described, it incorporates appropriate community legal instruments in order to ensure there are comparable basic levels of quality and safety throughout Member States.

Actions:

1) EU Directive on Quality and safety for the donation, procurement, testing, preservation, transport and distribution of human organs, under Article 152 of the Treaty

– Establishing common quality and safety standards for the authorization/accreditation/licensing of establishments and programs of organ donation and procurement.

– Ensuring quality management system, with a description of the standard operation procedures.

– Having a basic set of donor information and a system in place to facilitate the transmission of information within Europe, so that a proper risk benefit analysis can be made by the transplant team independent of the origin of the organ.

– Ensure effective preservation and transportation of organs to minimise ischemic times and avoid organ damage.

– Ensuring traceability and the reporting of serious adverse events and reactions.

2) Follow up the Greek initiative based on the results of the Europol report to evaluate how to tackle at least partly the issue of organ trafficking in the EC proposal based on art. 152.4 of the Treaty or to explore other possible initiatives to be undertaken on the basis of art. 29, 31(e), and 34(2)(b) of Title VI of the EU Treaty (third pillar)

6. ANALYSIS OF IMPACTS

6.1. Political impact

In 1958, the Council of Europe's Agreement No 26 on the exchange of therapeutic substances of human origin became the starting point for cross-border activities in this field. While specifically referring to human blood and its derivatives, provisions were made for the Agreement's extension to cover other therapeutic substances. Its main purpose was to facilitate exchanges of human substances between Member States of the Council of Europe in cases of urgent need and under the expressed condition that no profit was made. In 198616, the European Community became a contracting party to this Agreement. Subsequent agreements, recommendations and guidelines that have emanated from the Council of Europe for more than fifty years17 are the starting point for what now occurs in relation to safety and quality of substances of human origin in Europe.

In the resolution of the Council of ministers for health in 199118 concerning fundamental health choices the Council took note that the analysis of the Community's possible contribution concerning the availability of organs for transplants was identified as one of the topics which warrant join consideration, regular joint discussions and/or joint efforts to assist MS in framing their health policies.

In its 1994 report19 the Commission recommended the development of a blood strategy as a way towards restoring the confidence of Community citizens in the safety of the blood transfusion chain and fostering the goal of self-sufficiency. Council adopted the elements of this strategy in its 1995 Resolution[20.]

The reports throughout the eighties of blood contaminated with the human immunodeficiency virus (HIV) were undermining the public's confidence in the blood supply while at the same time, public health experts were continuing to try to prevent the transmission by blood and other substances of human origin of the main types of infectious agents – viruses, bacteria, and parasites.

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16 Council Decision 86/346/EEC, OJ L207, 30.07.1986, p.1

17 Genetet, B. Blood transfusion: half a century of contribution, Council of Europe Press, September 1998. 55p.

18 Resolution of the Council and the Ministers for health, OJ C304 23/11/1991 p5-6

19 Communication from the Commission on blood safety and self-sufficiency. COM(94) 652 final of 21.12.1994.

20 Council Resolution of 2 June 1995 on blood safety and self-sufficiency in the community, OJ C164. 30.6.95. p. 1.

The year 1997 was to see the Commission take a major step forward when it presented its first proposal21 under Article 129 of the Treaty of Maastricht. Adopted as a Council Recommendation22, it aimed to set forth common criteria for the acceptance of blood and plasma donors as well as a set of screening tests that should be carried out in all Member States, whether the donation was intended for transfusion or for further manufacturing into plasma-derived products.

However, it was the entry into force of the Treaty of Amsterdam that was to provide the Community with an opportunity to put into place a more coherent legislative framework to address the elements that had been set out in the blood strategy and to ensure a high level of safety for both donors and recipients. From 1999 onwards, with the adoption of the Treaty of Amsterdam, Article 152 has explicitly enabled the European Parliament and Council to adopt health measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives.

The Community has already adopted Directives of the Parliament and the Council on blood23 in 2003 and on tissues and cells24 in 2004. These laws have been followed by the adoption by the Commission (through the comitology procedure) of technical directives25,26,27,28 during the last years; the next step is to establish a set of non-binding initiatives to assist Member States to reach a consistent level of competence and performance.

The third step in this process would be to ensure the quality and safety of human organs. The European Parliament has already pushed to include organs in the scope of the tissues and cells Directive. At that time the Commission already recognised that organs needed a different approach from blood or tissues. Given the shortage of organs, the quality and safety aspects have to be considered fully within the framework of supply and demand.

This Commission Communication is responding to the mandate of the Treaty, which has been requested by the European Parliament and the Council of ministers. Furthermore, this Communication could support Member States in their efforts to strengthen public health policy and contribute to a better multi-stakeholder cooperation.

This is in close relation to the fact that organ shortage is a common dilemma in all European countries, and that sharing of expertise across the EU members has already proved useful in increasing organ donor rates in some countries. However, if the EU is pivotal to higher organ donation rates and more favourable results of organ transplantation, transplantation itself is paramount to Europe. Transplantation might contribute to reinforce the idea of Europe throughout its borders, to rekindle the spirit of community, especially after the recent enlargement of its members number. Transplantation requires striving for common objectives, sharing of experiences, active participation, and knowledge exchange. In a sense,

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[21] Commission proposal for a Council Recommendation on the suitability of blood and plasma donors and the screening of donated blood in the European Community. COM(97) 605 final of 17.11.1997.

[22] Council Recommendation 98/463/EC. OJ L 203, 21.07.1998, p.14.

[23] OJ L 33, 8.2.2003, p. 30–40

[24] OJ L 102, 7.4.2004, p. 48–58

[25] OJ L 91,30.3.94, p25-39

[26] OJ L 256, 1.10.2005, p 32-40

[27] OJ L 256, 1.10.2005, p 41-48

[28] OJ L 038 , 09/02/2006 P. 0040 - 0052

transplantation is a field where the ideals that laid the foundation of Europe are put into practice and may stand the test of time.

6.2. Economic impact

1) Treatment Costs: Diseases that can be treated or cured by transplantation usually carry a significant burden of morbidity and mortality, and therefore they have a significant impact on the national health care budgets. It is estimated that, at present, more than 3% of health care budgets of European Member Sates are dedicated to patients waiting for a transplant.

Organ transplantation provide the possibility of saving lives and also has the best cost / benefit ration in terms of economic gains as well as quality of life. It has been calculated that each 10,000 renal patients living with a functioning kidney graft are saving to health systems over 200 million € annually (in terms of differences of the economical costs of the different replacement therapies for end stage kidney patients, when comparing cost of transplantation versus costs of dialysis treatments). The average prevalence rate of end stage renal failure in Europe is around 1,000 patients p.m.p. Among those between 20 and 30% are waiting for a kidney. Annual incidence is around 140-150 new patients p.m.p. This is just taking into account daily dialysis costs and not including structural costs.

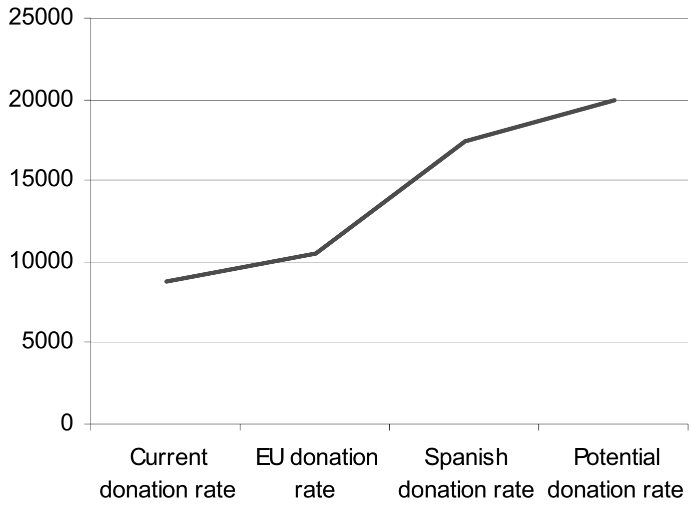
Cost-saving and cost benefits referred to Qualy's gains can be increased with a transplant. It has been defined that an increase of 6 donors p.m.p. in a country like Germany will lead to 29 Qualy's gains of patients with end-stage renal disease (calculation was made over a 20 years period).29

Recently several studies have shown that investing in organ procurement is clear a good health investment. Even considering the lack of data to complete the analysis, it is highly likely that obtaining additional donors will be cost effective even at a much higher average cost per donor

2) Productivity: The most important benefit for the grafted patients is measured in terms of survival and improvement of perceived quality of life, and consequently integration to the working and family life and productivity.

A raw estimation of the potential increase in donation rates in Europe could be done using different scenarios (achieving at least the European average donation rate in those MS that have lower rates, achieving the highest donation rate in Europe (Spain) in all MS and achieving the theoretical highest rate in all MS (40 ppm)) In all these scenarios the potential increase of organ donors is considerable (the figure below shows number of donors).

[29] Leo Roels, Bernard Cohen, Caroline Gachet and Blanca Miranda. Joining Efforts in Tackling the Organ Shortage: The Donor Action Experience. Clinical Transplants 2002;Chap. 8:111-120



The population in need of an organ transplant is on average a young population; with many productive years ahead,as the following table indicates:30

	Liver	Heart	Kidney	Lung
Average age at the time of the transplant	50.5	49.4	50.7	46.2
Average age in the Waiting list	50.7	48.9	50.5	47.6

Quality analysis and cost / benefit studies programmed for large samples and in different countries will definitely establish the need of a minimal invest in the organ donor promotion activities.

The next table shows the survival at 1, 3, 5 and 10 years posttransplant.31

Graft and patient survival at 1 year; 3 years, 5 years and 10 years post transplant				
Kidney				
Graft	88.4	78.5	63.3	36.4
Patient	94	88.4	79.9	59.4
Heart				
Graft	84.4	77.5	68.1	46.4
Patient	85.1	78.6	69.8	50

30 Data provided by the ONT (Spanish National Transplant Organisation)
31 OPTN/STR Data

Liver				
Graft	80.2	71.4	63.5	45.1
Patient	86.4	79.5	72.4	59.4

The Survival of patients without a transplant is clearly a worst scenario. For liver patients, we can rely heavily on analyses presented in the Institute of Medicine's (IOM's) 1999 study. It found that Status 1 patients on the waiting list are expected to survive only about one week without a transplant. For Status 2B patients, about 25% of those not transplanted would die within 12 months of listing; for Status 3 patients, about 10%.It could be assumed that all Status 1 patients and the great majority of Status 2A patients die within one month.

For heart transplant patients, we lack a data source like the IOM study and turn to the UNOS waiting list data. UNOS data for 2001 showed that those who were neither transplanted nor removed from the waiting list for reasons other than death had a survival rate of 46% at 6 months, 32% at 12 months, and 20% at 18 months.

Similar conclusions could be drawn for the quality of live with or without a transplant.[32]

3) Upgrading of organisational structures: This proposal will have an impact on the activities carried out within the Organ transplantation process. The establishments directly concerned by the provision of this proposal vary from hospitals or health centres where procurement is carried out, to third parties which can be responsible for some step of the process. The need of standards of quality and safety could increase the cost of the process. On the other hand they may help to reduce costs associated with adverse events and effects related to transplantation and facilitate the exchange of organs across the borders. There are not many cost benefit analysis of the introduction of quality and safety standards, and a detailed impact assessment should be done if the adoption of a Directive on quality and safety is decided.

The latest analysis has been undertaken by Health Canada on the introduction of the new CSA standards for blood, cells, tissues and organs. The conclusion of this analysis indicates the strength of the case in favour of adopting the regulation clear rest on the discounted benefits from extending lives. The analysis of avoided costs indicated that hospitals may not recover their incurred costs in implementing the new standards. Benefits are concentrated in the provision of better services to patients and mainly conferred on those patients through extension of their lives and the quality of their lives. In conclusion for every standard, estimated benefits over the next 20 years exceed costs by significant amounts. In particular the benefits associated with implementing the standards on quality and safety in Canada for perfusable organs for transplantation over the next 20 years discounted at 5 % per year were estimated to be between $759.3 million and $1.4 billion; costs to organ donation organisations and organ transplant programs to meet these standards were estimated at $202.8 million. Obviously these calculations can not be directly transposed to the EU situation.

6.3. Assessing the impact on health and social welfare

1) Increasing organ availability will have an impact on the increase of organ transplant and thus increase healthy life years. As mentioned in this document Organ transplantation is now

32 Mendeloff J; Ko K Roberts MS, et al. Procuring organ donors as a health investment: how much should be willing to spend? Transplantation 2004; 78:1704.

the most cost-effective treatment for end-stage renal failure, and for end-stage failure of organs such liver, lung and heart, it is the only available treatment. Both quality/safety and availability will have an impact on the improvement of quality of life and reduced suffering for many patients and their families

Mean expected half-life for a deceased kidney grafted in the USA has increased by 75% from 1988 to 1996, rising from 7.9 to 13.8 years. When adjusted to exclude dead patients with functioning graft, these data are 11 and 19.5 years respectively [33]

Ten years survival rate for liver transplantation was 31% before 1988 and it has been improved to nearly 60% in most European countries[34]. According to the Registry of International Society for Heart and Lung Transplantation and the UNOS Registry, lung survival has increased from 70.9% to 76% between 1990 and 199735.

Investment in organ procurement has proved to have a net social benefit. Other alternatives such the use of living donation or the use of expanded donor has to evaluated. It is obvious that there is a need to increase the number of available organs but not at any price. Safety and quality levels need to be established at the same time.

2) The use of organs in therapy poses a risk of communicable diseases being transmitted to the recipient. Because organs cannot be subjected to sterilization steps, the risk of infectious disease transmission remains and thorough donor screening and testing is especially important.

Basic quality and safety requirements will have an impact on risk reduction and consequently in reduction of comortality and comorbidity.

To minimise the risks to the recipient, it is essential to screen donors and establish the presence or absence of disease transmission risk in their organs. Pre-transplant evaluation of potential donors is an essential part of solid organ transplantation. The goals are to identify conditions which disqualify donors; to identify and active infection pre-transplant and to define the level of risk in order to determine strategies for preventing post-transplant effects.

In the other side a very stringent set of binding safety and quality criteria could have as a consequence a reduction in the actual number of donors. The fundamental premise is that organs from donors with positive viral serology or history of malignancy are underutilised because their organs might transmit disease. It is important a clear understanding of the disease transmission risk inherent in each case. Although a definition of risk based upon the profile is critical to rational decision-making, each decision also depends upon recipient characteristics.

3).The new Member States face greater health problems than the rest of the Union but have less economic means to address them. Their health systems are therefore under particular pressure, in particular when it comes to the process from organ donation to transplantation, which is such a complex process that it could be especially difficult to address. This leads to

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33 Hariraran S. Johnson CP., Bresnatian BA., Taranto SE., McIntosh MJ., Stabilein D. Improved graft survival after transplantation in the USA. 1988-1996. N.Eng.J.Med. 2000; 342:605-612.

34 European Liver Transplant Registry Report. www.eltr.org., Spanish Liver Transplant Registry Report.www.msc.es/ont. Updated Sept. 2003.

35 UNOS Registry Data. www.unos.org. Updated daily

enormous differences within Member States in terms of accessibility to transplants and the length of waiting lists. Collaboration at EU level can bring particular benefits to those systems and favour the accessibility to these therapies to an important number of European citizens.

6.4. Environmental impact

There is no significant impact on environment.

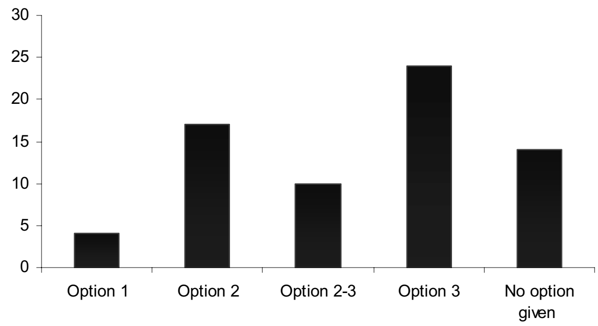
7. COMPARING THE OPTIONS

7.1. Summary of contributions of the open consultation

General comments

A vast majority of respondents welcomed the Commission's consultation paper, the opportunity to submit contributions, and explicitly supported the outlined objectives. The support for an EU action in this field was strongly emphasised. Broadly speaking, most of the contributors agreed with the key principles and concepts underlying the Commission's consultation document.

There is a general consensus on the importance of ensuring the quality and safety of organs for transplantation at EU level. Given the current situation of organ shortage, diverse opinion came out during the consultation on how should be the best approach to this objective. A major number of responses opted for option 3 (incorporating a Directive on organ quality and safety); however an important number of responses considered option 2 (guidelines through a strength cooperation method) as the preferable one.

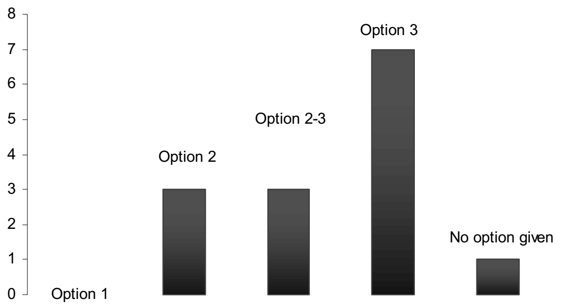


Others considered Option 2 as a "phasing in period"; and in the light of the work done through the coordination method, the introduction of additional legislative instruments could be considered. This option has been named as option 2-3 and also incorporate the responses in favour of option 2 plus an initiative on organ trafficking but not a quality and safety Directive.

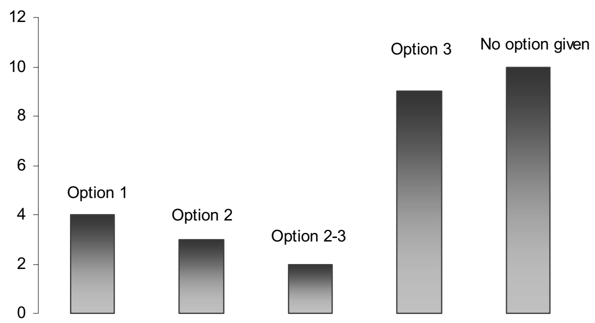
Many responses did not refer to particular options but gave interesting suggestions on different types of activities that could be undertaken at community level.

Among the different categories of stake holders professionals, patients and donor associations were majority supported to the third option.

Patients/donor assoc.

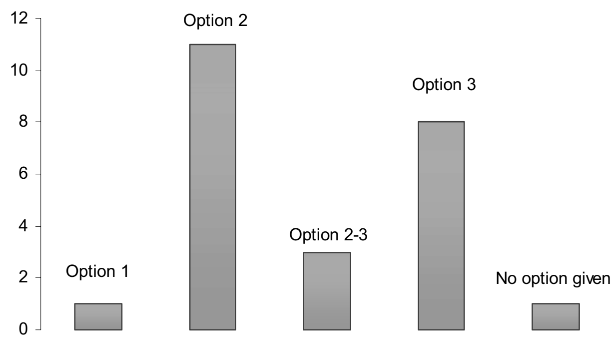


Professionals/Scientific ass



Should be pointed out that many of the stakeholders categorised into the professional/scientific association have provides a good number of comments on possible initiatives but without pointed out any specific option.

Organ Exchange Organisations (OEOs), National Agencies or public authorities are more comfortable with the second option, although the support for the third option is also considerable.



There is however a general agreement that the content of a hypothetic future directive should be limited to establish a basic quality and safety framework for Europe and at the same time should respect the clinical decision. Binding requirements should not represent any barrier for organ donation, including the use under specific circumstances of the so call “expanded donors”. A comprehensive assessment of the impact should be presented with the proposal.

There is a common agreement that Organ shortage is the main problem in the field. There is also a majority of responses recognising the European added value of a Community action in this field, only four among all the responses were against this general feeling.

Developing national or regional systems to an optimum level of performance is a prerequisite for wider European cooperation. These systems need an appropriate legal framework, a good technical approach and organizational support. Sharing best practices and expertise, getting the best of the best models are some of the suggestion received.

For most of the participants a centralised European donor pool is not considered an option. However contributors pointed out the added value on many European actions through an active cooperation between Member States or existing OEOs, some of the actions mentioned were the coordination of training of professionals, performing of a benchmark between Member States to identify areas of improvement and determining priorities, coordination of programmes oriented to facilitate the identification of organs for urgent patients and highly sensitised patients, mainly in those small EU countries with limited size of their national donor pools. Other actions identified were the development of consensus guidelines and professional standards to ensure good medical practices or the evaluation of post transplant results "organovigilance" including adverse event to lead to a safer and more effective use of organ donors.

Promotion of the donation is also one of the most shared suggestions received during the consultation. Awareness-raising activities have been suggested, it has also mentioned the need to give to these activities a society oriented approach. The involvement of all stakeholders in the process (regulators, health care professionals, patients and donors associations, media, opinion and religious leaders, educational professionals, judges, etc…) has been pointed as a key factor for success.

Many contributors pointed out that the use of living donors should be promoted

Accessibility of transplants have been recognised as a problem not only between Member states but also within the member states, partially as a consequence of the ever shrinking donor rate, but also has been pointed out that there are huge differences in access that cannot merely be explained by differences in organs donor rates.

It has also pointed out that the accessibility to transplantation as a complex issue, like other healthcare access issues and that it cannot be separated from it general healthcare environment. Coordination between Member states will certainly be a factor to improve the situation but will not be the only one. Access to transplant requires for example financial and human resources on the long run.

Some contributions underlined the phenomenon of transplant tourism (potential recipients from one country trying to get a transplant in another country with higher donation rates than in their own country). An issue has been identified as not been addressed in the consultation document, the growing number of non-EU citizens waitlisted for organ transplantation, namely in regions of the European borders. This increases the current shortage of organs and at the same time faces the EU with ethical dilemmas.

There is a general support of exploring initiatives to combat organ trafficking

7.2. Comparison of the options

a) First level: Use of existing programmes only

ADVANTAGES	DISADVANTAGES
Projects funded by the Commission and carried out by selected consortium have been proved as a valuable tool to progress forward a better understanding of the problems and finding possible solution. These programs have involved the professionals on the field and offer enough flexibility for Member States to tailor the results of the initiatives to their own national situations.	However it is also recognised that the coordination of these projects under different Community programmes is quite difficult and that a coordinate action taken into account the results of all the initiatives and avoiding overlapping is the most efficient choice. The participants in these projects do not always represent all Member States, in the contrary many times the best establish systems are leading the projects and the results will not probably benefit to the whole Community. The projects have a limited time frame and limited resources with the risk that once the project is finished the continuity of the results is not ensured. In addition the projects not always have the capacity to transform the results of their investigation to the political level in order to make them operative. Finally the projects will be seen as one of the tools possible to ensure a high quality of organs but they do certainly not qualify as harmonising measures under Art. 152.4 which expressly confers powers to the legislator to adopt harmonised measures in this specific field.

b) Second level: Active coordination between Member States on organ quality, safety and availability.

ADVANTAGES	DISADVANTAGES
It is very important that further work under the exiting programmes is continued and extended involving Member States and relevant stakeholders. However the outcome of these projects will only be useful if health authorities will abide by	This option will address the real main problem identified by the experts: the organ shortage. However national legislations differ between Member States A national approach would not solve completely the quality and safety

their conclusions. The development of pan European cooperation, sharing best practices, common safety and quality standards, and the promotion and maximisation of organ donation would all be beneficial in developing agreed quantitative and qualitative indicators and benchmarks and aid future development of EU policy in the light of further information and experience. The Community should get the best of the best models and support its application in the entire EU. It is clear that what Europe needs is not so many short-lived programs that are hard to translate into real practice, but rather a full flagged agenda of priorities. The Strength cooperation will not only help to develop the national transplant systems – a prerequisite for cooperation in this field- but also will identify and foster a number of activities that only can be carried out –or at least with better result s-at European level. Promoting the coordination between MS should be the main objective; these actions must work with a minimum of red tape, work load and cost. Emphasis should be on collaboration and sharing best practices, taking into account the differing circumstances of each member state and not setting uniform targets across member States.	objective, in addition there are still a number of European factors that have to be taken into account, i.e. organ interchanges within the community. Coordination between MS has often proved not to be such an effective tool without any legal instrument supporting the actions. Thus, this would most likely lead to not fully meet the objectives under Article 152. Basic common binding principles should be in place to allow a smooth cooperation.

c) Third level. Second level + Minimum harmonisation on quality and safety + initiative on Organ trafficking

ADVANTAGES	DISADVANTAGES

An appropriate and flexible European legal framework is a better response to the requirements under Article 152 of the Treaty on quality and safety. Finding the appropriate risk-benefit balance for the patient is a key aspect. While respecting the clinical role of the doctor in the decision on the acceptance of organs for transplantation, community binding legislation would have an added value in terms of ensuring the basic quality and safety requirements across the Community. Every year, a number of organs are exchanged between EU Member States. Cross border exchanges imply that the transplantation process is carried out by hospitals or professionals falling under different jurisdictions. The increasing phenomenon of transplant tourism (potential recipients from one country trying to get a transplant in another country with higher donation rates than in their own country) is a reality. Having common binding standards of quality and safety will be the only mechanism to ensure the same health protection all along the EU. Establishing a regulatory Committee under a Community Directive will facilitate the coordination activities within Member States. In addition would show leadership on pan European level and encourage those non EU European Countries currently without any form of transplant legislation to give serious and formal consideration to all areas of the transplantation process It should be explored how the initiatives under Article 152 could address the issue of organ trafficking and/or if they have to be complemented with initiatives under Articles 29, 31(e), and 34(2)(b) of the EU Treaty (JLS), oriented to combat Organ trafficking in order that the EU could be	The legislative proposal may have difficult practical consequences for MS which in turn may lead to an actual decrease in number of donors. It could be seen as a burden for the organisation of transplants and patient accessibility. This area relates closely to "medical treatment" where the role of the medical doctor is a key factor and thus should be left to MS, where it could be addressed in a more efficient way. Some MS are had reservation in the past in relation with Organ trafficking. The problem of Organ trafficking seems to occur outside of the EU. It seems that patients from EU MS, who are waiting for transplants, travel to third countries in order to receive donation which has been taken forcibly or by a payment (usually low).

seen to be acting proactively rather than reactively.	

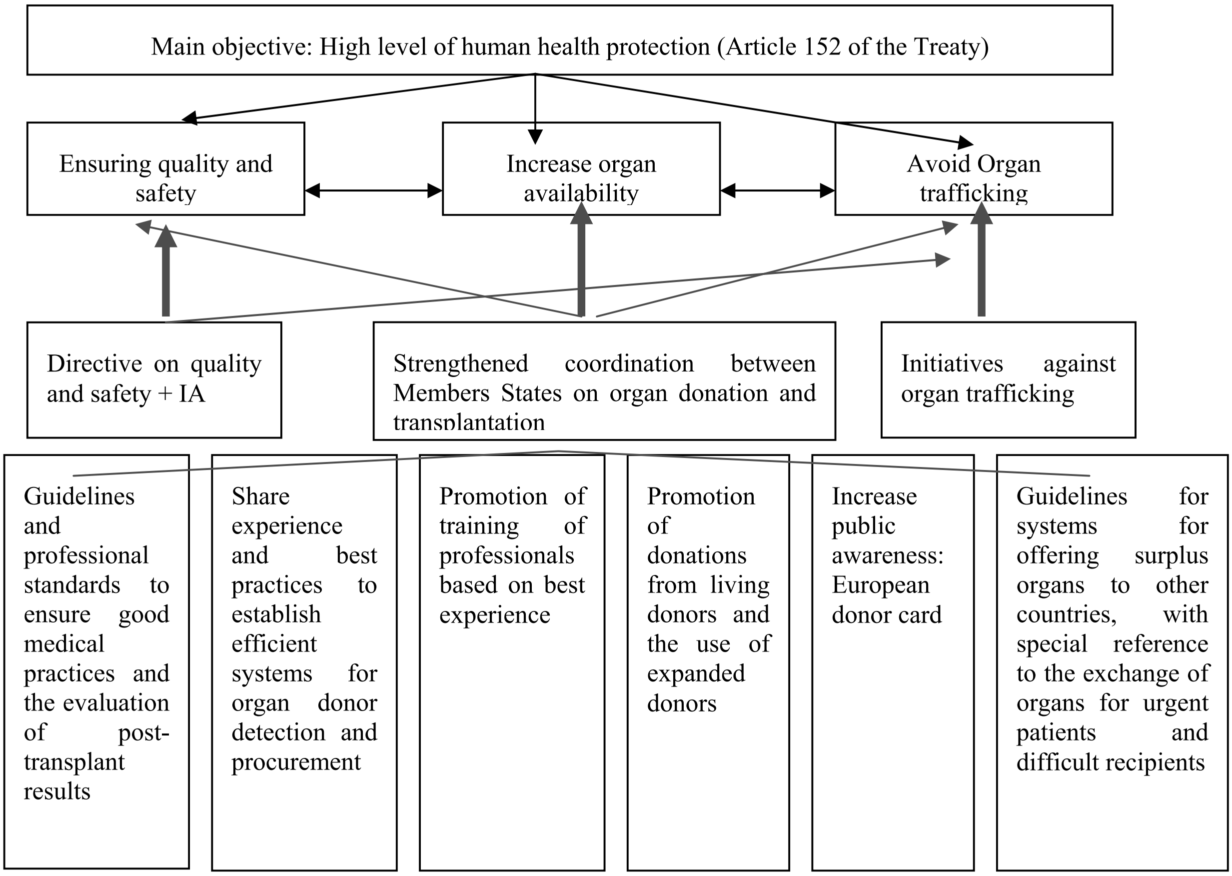
7.3. Conclusions

Undoubtedly an EU initiative on organ donation and transplantation has an added value.

The use of an open method of coordination, specifically adapted to this concrete field, and as a complement to the legislative framework, will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach will be based, in the first stage at least, on the identification and development of common objectives for which it is agreed that a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

The preferred option

The Commission propose a combined set of actions to respond to the proposed objectives, this option could be represented as follows:



As first level of intervention the work under the deferent Community programmes should continue during the coming years. It is important that the results of these projects, such European registers on activities in this field with agreed methodology, coordination between research programmes or development of methodologies to increase organ donation, have continuity and are adopted at political level, these initiatives should also be made accessible to all the Community.

Strengthen the cooperation between Member states, specifically adapted to this concrete field, will provide the necessary policy mix to achieve a gradual approach to the development of an EU policy. This approach will be based, in the first stage at least, on the identification and development of common objectives for which it is agreed that a Community response is necessary, on agreed quantitative and qualitative indicators and benchmarks, regular reporting and identification of best practices.

The Commission in collaboration with Member States should determine common EU guidelines for national polices, formulate the objectives for the short, medium and long term and describe the instruments and methods needed.

The Commission in collaboration with Member States should define the exact and balanced scope of the EU legal framework on quality and safety for human organs and present a

proposal to Parliament and Council, a comprehensive assessment of the impact should be attached to the proposal. The future proposal should establish a basic quality and safety framework for Europe. Binding requirements should not represent any barrier for organ donation, including the use under specific circumstances of the so call “expanded donors”. A comprehensive assessment of the impact should be presented with the proposal.

This legal framework should be complemented with the cooperation between Member States leading to the compilation of sufficient information that will assist in determining the acceptable levels of risk in the use of expanded donors and the promotion of consensus guidelines and professional standards to ensure good medical practices and the evaluation of post transplant results: “organovigilance”

The Commission should promote cooperation between Member States on sharing experiences and best practices oriented to establish efficient systems for organ donor detection and procurement. The objective should be to get the best of the best models while respecting the cultural and organisational diversity.

Other areas where active cooperation is important to increase organ availability are the promotion of training of professionals based in the best experiences; to explore the promotion of donations from living donors, to evaluate the procurement of organs from non-heart-beating donors; and the use of “expanded donor” taking into account the quality and safety aspects mentioned in the previous section.

It will be also important to join efforts and expertise in order to increase public awareness. In this context the creation of a European organ donor card or its incorporation on the existing health card should be considered.

Healthcare access issues cannot be separated from it general healthcare environment and has to be seen in relation with other initiatives at community level in this area.

It should be focus in identifying the most efficient systems, sharing experience and promoting best practices in accordance with local characteristics. Those Member States whose transplant systems are not yet sufficiently developed could be supported and guided in their efforts to improve patient care

Other actions should be oriented to identify the needs at EU level for the interchange of organs. Guidelines for systems for offering excess organs to other countries could be evaluated and in particular exchange of organs for urgent patients and difficult recipients (e.g. children, highly sensitive patients).

The increasing mobility of people within the EU makes necessary to identify the main problems on patient mobility. It will be also important a EU-wide agreement on all issues concerning transplant medicine for extra-Community patients ("non-residents").

Finally it will be needed to explore how the initiatives under Article 152 could address the issue of organ trafficking and/or if they have to be complemented with initiatives under Articles 29, 31(e), and 34(2)(b) of the EU treaty (third pillar)

An assessment of the specific measures once decided should be done and presented with the proposals, for each particular initiative the benefits should be quantified and contrasted with the degree of intervention in so far as this is possible.

8. Monitoring and evaluation

As stated in the EC Impact Assessment Guidelines (SEC (2005) 8 June 2005) the road map for monitoring progress should "set measurable indicators to cover both the quality of outcomes and the implementation process, and define plans for evaluation."

The structure of the Communication and the annexed Action Plan provides that for each aim there are actions. Indicators, timeframe and responsible parties will be identified and developed in cooperation with relevant partners/stakeholders.

Annex I Medical Background Information

TRANSMISSION OF COMMUNICABLE DISEASES.

Human immunodeficiency virus (HIV). The majority of the cases of HIV-1 transmission through organ transplantation were described before the existence of the serological tests. However there are also cases of HIV-1 transmission described after the introduction of the tests, they were false negatives during the “window” period –the time delay between viral exposure and detectible antiviral antibodies36. There are not cases described of HIV-2 transmission.

The effectiveness of the transmission is difficult to know, but it is assumed that is nearly 100% through solid organ transplantation from a donor HIV positive[37]. HIVAc (+) donors carry a high risk of viral transmission, the infectivity of a small inoculum has been demonstrated by blood transfusion studies4.

All potential organ donors have been screened for HIV since 1985. The rare instances of HIV transmission despite negative HIVAc test results illustrate some limitations of serologic testing. In one instance, massive transfusion of blood and blood components decreased the antibody titer below the sensitivity limits of EIA. In a second case, transmission occurred from a donor during the “window period”.

The transmission through these false negatives should be prevented through a good clinical and behavioural history of the donor. See point 3 and 4 below.

Hepatitis B virus (HBV). The cases of HVB transmission have decreased due to the serological screening, which normally includes Ag HBs test.

Kidney was the first graft involved in a case of HBV transmission.

There are studies that indicate that more than 1% of potential donors have an active HBV infection and over 12% in hyper endemic areas. 3-4% donors have a past history of HBV infection in countries with low prevalence like USA and over 10% in some European countries.

The risk of transmission from donors with test against Antigen Hepatitis B (Ag HBV) positive is nearly 100%. However the transmission of HBV to the recipients is also possible from donors Ag HBV negative that have other serological markers positives38.

The risk of transmission by liver transplantation from a donor with a serological antibody (HBVAb) test positive against hepatitis B is higher because HBV resides principally within

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36 Screening of donor and recipient prior to solid organ transplantation. American Journal of Transplantation 2004 (Suppl. 10): 10-20

37 Criterios de selección del donante de órganos respecto a la transmisión de infecciones. 2ª edición. 2004. Organizacion Nacional de Transplantes. http://www.ont.es/Consenso?id_nodo=263&&accion=0&keyword=&auditoria=F

38 Feng S.; Buell J.F. Cherikh W.S., et al. Organ donors with positive viral serology or malignancy: risk of transmission by transplantation. Transplantation 2002; 74 (12): 1657-1663

the hepatocytes [4,39],[40]. The donor´s Hepatitis B Antigen status do not mitigate transmission risks[41]. This type of donors represent in some countries between the 5-15% of all donors[42].

In contrast with liver transplantation, transplantation of kidneys from HBcore antibody positive donors seems to carry a minimal risk of clinical transmission. A meta-analysis of the literature shows that only 1 of 133 recipients converted to HBs Antigen positive after transplantation of a kidney from an HBc antibody positive donor[43] [44].[14]. It should be noted, however, that the actual rate of viral exposure as measured by development of anti-HBV antibodies (either HBsAb or HBcAb) is considerably higher. 27 % of kidney recipients from HBcAb + donors demonstrated seroconversion compared with 4% of kidney recipients from HBcAb - donors, for an odds ratio of 4.94 4.

Some studies indicate that the risk of transmission is 15-78% for liver transplantation, 2% in kidney and 0% in heart transplantation.

An additional problem that could be found in donors Ag HBs positive is the co-infection with the virus of hepatitis delta (VHD). It has been described the transmission of this virus trough kidney transplantation resulting on severe acute hepatitis.

Hepatitis C virus (HCV) Transplantation of an organ from an HCV+ donor is known to be an efficient mode of viral transmission 4,[45],[46],[47],, . Approximately 5% of all potential donors in USA and Europe are positive for Antibody HCV[48].

A positive HCV-RNA, indicative of viral replication, has been associated with a higher risk of transmission.49. The transmission from donors with RNA positive is estimated to be nearly 100%. The risk of transmission from a non RNA positive donor is not known.

The consequences for the recipient of an organ from a HVC positive donor are the seroconversion in 50-67% of the cases and the percentage of development of hepatic disease is around 35%.

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39 Dodson SF, Issa S, Araya V, et al. Infectivity of hepatic allografts with antibodies to hepatitis B virus. Transplantation 1997; 64 (11): 1582

40 Uemoto S, Sugiyama K, Marusawa H, et al. Transmission of hepatitis B virus from hepatitis B core antibody- positive donors in living related

41 Dickson RC, Everhart JE, Lake JR, et al. Transmission of hepatitis B by transplantation of livers from donors positive for antibody to hepatitis B core antigen. The National Institute of Diabetes and Digestive and Kidney Diseases Liver Transplantation Database. Gastroenterology 1997; 113 (5): 1668.

42 Data from ONT, Spain

43 Madayag RM, Johnson LB, Bartlett ST, et al. Use of renal allografts from donors positive for hepatitis B core antibody confers minimal risk for subsequent development of clinical hepatitis B virus disease. Transplantation 1997; 64 (12): 1781.

44 Satterthwaite R, Ozgu I, Shidban H, et al. Risks of transplanting kidneys from hepatitis B surface antigen- negative, hepatitis B core antibodypositive donors. Transplantation 1997; 64 (3): 432.

45 Wreghitt TG, Gray JJ, Allain JP, et al. Transmission of hepatitis C virus by organ transplantation in the United Kingdom. J Hepatol 1994; 20 (6): 768

46 Tesi RJ, Waller K, Morgan CJ, et al. Transmission of hepatitis C by kidney transplantation–the risks. Transplantation 1994; 57 (6): 826.

47 Pereira BJ, Wright TL, Schmid CH, Levey AS. A controlled study of hepatitis C transmission by organ transplantation. The New England Organ Bank Hepatitis C Study Group. Lancet 1995; 345 (8948): 484.

48 Candinas D, Joller-Jemelka HI, Schlumpf R, et al. Hepatitis C RNA prevalence in a Western European organ donor pool and virus transmission by organ transplantation. J Med Microbiol 1994; 41 (4): 220.

49 Fishmen JA, Rubin RH, Koziel MJ, Pereira BJ. Hepatitis C virus and organ transplantation. Transplantation 1996; 62:147-154.

Overall, limited available data validate the assumption that heart or lung transplantation presents a similar risk of HBV or HCV transmission as kidney transplantation. Finally with regard to outcome, no conclusions can be drawn because the specific impact of the donor's positive serology cannot be discerned from the available data.

Other Viruses Human T- Linphotrofic virus (HTLV-I and II) is endemic in certain areas; out of these areas the prevalence of this infection is low (lower that 1 % or even 0.1%). Infection with HTLV progress after years or decades to associated myelopathy spastic paraparesis or to adult cell leukaemia/lymphoma (ALT); progression occurs in less that 1% and 2-'% respectively. Cases of ALT after transplantation have been reported.

West Nile virus (WNV) is a flavivirus which can cause meningoencephalitis. In the fall of 2002, transmission of WNV from a single donor to four organ donors has been reported. An additional case through liver transplantation has appeared. In August 2002, fever and mental-status changes developed in recipients of organs from a common donor; transmission of WNV through solid organ transplantation was suspected. Transplant recipients can acquire WNV in 1 of 3 ways: (1) transfusion transmission, (2) organ donor transmission, and (3) transmission in the community. Posttransplant immunosuppression increases the risk of developing severe disease after WNV infection. In the general population, WNV causes severe neurologic disease in < 1% of infected patients. However, data from a seroprevalence study suggest that the incidence is as high as 40% in organ transplant recipients.

Although prevention strategies are critical, there is disagreement within the transplant community about the use of nucleic acid testing for screening of organ donors for WNV because screening results can be affected by a number of factors, including local WNV activity, test availability, and test characteristics.

Bacterial and fungal infections. A bacterial or micotic infection or colonisation can be present in 60 % of deceased organ donors and mainly affect the respiratory and urinary tract. Bacterial and fungal donor to host transmission with the allograft with result of loss of the infected graft or death of the recipient has been widely documented. Nevertheless an adequate antibiotic treatment of donor and/or recipient should prevent infection in the latter.

Micobacterium tuberculosis has been transmitted by transplantation, donor transmission accounted for approximately 4% of reported post-transplant TB cases in a large review of 511 patients50.

Transmission of histoplasmosis by transplantation has been described, but most cases appear to be the result of reactivation of past infection in the recipient. Transmission of Coccidiodomycosis by lung transplantation has also been reported.

Parasitic infections

There are 342 parasitic species that are known to infect humans, mostly affecting those in tropical and subtropical regions51. Recently however there are been a considerable spread of

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[50] Singh N; Paterson DL; Mycobacterium tuberculosis infection in solid organ transplantation recipients: impact and implications for management. Clin infect Dis 1998; 27 1266-77

[51] RS Barsoum Parasitic Infections in Organs transplantation. Experimental and clinical Transplantation Vol 2. 2. December 2004

these infections to the rest of the world as result mainly of travel and migration. Only 5% of the known human pathogenic parasitic infections have been reported in transplant recipients.

Malaria transmission has been reported with kidney, bone marrow and multi-organ transplantation. Toxoplasmosis is a major concern particularly on heart transplantation. Toxoplasma has rarely been transmitted to liver and kidney recipients.

Transmission of Chagas diseases is a significant problem in endemic areas, and recently has been reported in the US.

Prion infections

Creutfeld Jacob disease has been transmitted with treatment with growth factors and with transplantation of cornea and duramater grafts. In July 2004, the United Kingdom announced that a second instance of probable vCJD (new variant) transmission via blood transfusion had been identified. The patient received the blood donated by an individual who was confirmed in 2001 as a definitive vCJD case.

TRANSMISSION OF MALIGNANT DISEASES

United Network for Organ Sharing (UNOS) transplant tumour register[52]	First report of the UNOS (1994-96) showed a frequency of donors with malignant cancer history of 1.7% and a rate of transmission of cancer from donor to recipient of 4.3%.
	A more recent report from this registry (1994-2000 period) showed 14 donors with tumour from a total of 35.503 donors (4 per 10.000) and tumour transmission to 15 recipients of 109.749 transplants (1.3 per 100.000). The tumors transmitted were the following: 4 melanomas, 1 neuroendocrine tumor, 1 adenocarcinoma, 1 cancer of the pancreas, 1 nondifferentiated squamous carcinoma, 2 lung cancers, 1 small cell carcinoma, 1 oncocytoma, 1 papillary tumor, 1 breast cancer, 1 prostate cancer)
Organización Nacional de Transplantes (ONT) register	The frequency of donors with no detected tumour was 6.1 per 1000 donors during the last 15 years. Five of these donors transmitted the disease (2.9 per 10.000 donors). Ten recipients of the 155 that received an organ from a donor with undetected cancer developed a tumour (4.6%). The tumours transmitted were 1 sarcoma, 1 germ cells carcinoma, 1 undifferentiated

52 Kauffman HM, McBride MA, Delmonico FL. First report of the United Network for organ sharing transplant tumor registry: donors with a history of cancer. Transplantation 2000; 70 (12): 1747-51

	carcinomatosis and two kidney carcinomas.
Danish Register[53]	Bikerland studied a cohort of donors during 27 years funding 13 malign tumours within 626 donors (2% of the donors) From these donor only one has transmitted the tumour (a melanoma) to the recipient (2 per 1000 donors)
Centro Nazionale per i Trapianti (CNT) register	The CNT has put in place a new strategy for the evaluation of donors since 2002. The analysis of the period 2001-2002 showed 2.9 % of donors with tumours.
The Israel Penn International Transplant Register. (IPTTR)[54]	The I. Penn register shows higher frequencies of tumour transmission that the ones above. During 1994-2001 it registered 68 recipients of organs coming from donors with renal carcinoma, with a tumour transmission in 43 of them (43%). 30 recipients of organs received from donors with melanoma, with tumour transmission in 23 (77%); 14 recipients received from donors with melanoma, 14 recipients with coriocarcinoma, with tumour transmission in 13 (93%). Other tumours that have presented transmission to recipients were lung (41%), colon (19%), prostate (29%), Kaposi Sarcoma (67%).

53 Arvid Bikerland S, Storm H. Risk for tumor and other disease transmission by transplantation: a population-based study of unrecognized malignancies and other diseases in organ donors. Transplantation 2002; 74 (10): 1409-13

54 Feng S, Buell J, Cherikh WS, Deng MC, Hanto DW, Myron Kauffman H, Leichtman AB, Lorber MI, Maters RG, Mcbride MA, Metzger RA, Nolte FS, O´Connor KJ, Roth D, Terrault NA, Henry M. Organ donors with positive viral serology or malignancy: Risk of disease transmission by transplantation. Transplantation 2002; 74 (12): 1657-1663

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